

Exhibit D

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UNITED STATES DISTRICT COURT

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SOUTHERN DISTRICT OF WEST VIRGINIA

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CHARLESTON DIVISION

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IN RE: ETHICON, INC., PELVIC Master File No.

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REPAIR SYSTEM PRODUCTS 2:12-MD-02327

8

LIABILITY LITIGATION MDL No. 2327

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THIS DOCUMENT RELATES TO ALL

11

WAVE 5 AND SUBSEQUENT WAVE CASES

JOSEPH R. GOODWIN

U.S. DISTRICT JUDGE

12

AND PLAINTIFFS

13

Betty McCumber

14

Case No. 2:12-cv-08083

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General re TVT

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General re TVT-O

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Deposition of

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RAGNVALD MJANGER, M.D.

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taken on Thursday, July 20, 2017

23

commencing at 9:03 a.m.

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REPORTER: Sandra D. Burch, RPR, CRR

Ragnvald Mjanger, M.D.

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APPEARANCES:																								I N D E X																							
FOR THE PLAINTIFF:																								(Continued)																							
ANDREW N. FAES, ESQ.																								EXHIBITS:																							
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<p style="text-align: right;">Page 6</p> <p>1 A Yes, I do.</p> <p>2 Q And I'm here today to take your deposition</p> <p>3 regarding the TVT and TVT-O products.</p> <p>4 Do you understand that?</p> <p>5 A Yes, I do.</p> <p>6 Q And you understand you're under oath and</p> <p>7 sworn to tell the truth; right?</p> <p>8 A I do.</p> <p>9 Q I think you've only ever given one</p> <p>10 deposition before; is that right?</p> <p>11 A I've given multiple.</p> <p>12 Q Okay. But in the last five to ten years,</p> <p>13 you've only given one?</p> <p>14 A No. I've given several.</p> <p>15 Q We'll get into that later. So, you kind of</p> <p>16 understand the process. Let me reiterate</p> <p>17 that if I ask a question at any time today</p> <p>18 that, for any reason, doesn't make sense to</p> <p>19 you, just let me know and I'll try to</p> <p>20 rephrase the question.</p> <p>21 Okay?</p> <p>22 A Okay.</p> <p>23 Q If you do answer my question, I'll assume</p> <p>24 that you understood my question as asked.</p>	<p style="text-align: right;">Page 8</p> <p>1 A No.</p> <p>2 Q Okay. And what is your understanding of</p> <p>3 what's on this flash drive that's in front</p> <p>4 of us?</p> <p>5 A It's various articles about the mesh in this</p> <p>6 case.</p> <p>7 Q So, it's just articles? Is that your</p> <p>8 understanding?</p> <p>9 A I can't remember everything, unless you put</p> <p>10 it in front of me on a hard copy.</p> <p>11 MS. VAN STEENBURGH: I'll</p> <p>12 represent to you that we put that together</p> <p>13 and it's all of the reliance materials that</p> <p>14 are on the list that was provided to you</p> <p>15 before.</p> <p>16 MR. FAES: Okay.</p> <p>17 BY MR. FAES:</p> <p>18 Q I don't know if you know the answer to this,</p> <p>19 but is there anything on this flash drive in</p> <p>20 front of me that -- is there anything that's</p> <p>21 on the flash drive that's not already</p> <p>22 reflected on your reliance list that was</p> <p>23 served with your expert report?</p> <p>24 A No.</p>
<p style="text-align: right;">Page 7</p> <p>1 Fair enough?</p> <p>2 A I understand.</p> <p>3 Q All right. Doctor, I'm going to mark as</p> <p>4 Exhibit No. 1 the notice of your deposition</p> <p>5 today because it's like our thing to do as</p> <p>6 lawyers.</p> <p>7 (Exhibit No. 1 Marked.)</p> <p>8</p> <p>9 BY MR. FAES:</p> <p>10 Q And this is the notice of your deposition</p> <p>11 here today, and it contains various document</p> <p>12 requests.</p> <p>13 Have you seen that document before?</p> <p>14 A (Witness reviews the document.)</p> <p>15 I have.</p> <p>16 Q And counsel has brought a material of flash</p> <p>17 drives.</p> <p>18 Other than this material of flash</p> <p>19 drives that's in front of me that's marked</p> <p>20 Mjanger, is there anything else that you</p> <p>21 brought here today that's responsive to the</p> <p>22 document requests --</p> <p>23 A No.</p> <p>24 Q -- in the notice?</p>	<p style="text-align: right;">Page 9</p> <p>1 Q And is there anything on your reliance list</p> <p>2 that wouldn't be on the flash drive that you</p> <p>3 know of?</p> <p>4 A Not that I recall, no.</p> <p>5 Q And Doctor, I'll mark Exhibit No. 2 to your</p> <p>6 deposition.</p> <p>7 (Exhibit No. 2 Marked.)</p> <p>8</p> <p>9 BY MR. FAES:</p> <p>10 Q And can you tell me what that is?</p> <p>11 A This is the statement that I made about this</p> <p>12 case.</p> <p>13 Q So, this is your expert report regarding the</p> <p>14 TVT and TVT-O dated June 14th of 2014;</p> <p>15 right?</p> <p>16 A That is correct, yeah.</p> <p>17 Q And that's when you signed this report?</p> <p>18 A That's correct.</p> <p>19 Q Does this report contain each of the</p> <p>20 opinions that you reached regarding the TVT</p> <p>21 and TVT-O products?</p> <p>22 A Ask that again.</p> <p>23 Q Does this report marked as Exhibit No. 2</p> <p>24 contain each of the opinions that you've</p>

<p style="text-align: right;">Page 10</p> <p>1 reached regarding the TVT and TVT-O</p> <p>2 products?</p> <p>3 A Yes, it do.</p> <p>4 Q Yes, it does?</p> <p>5 A Yes, it does.</p> <p>6 Q Okay. Now, in this report, you go through</p> <p>7 various facts and discuss various articles.</p> <p>8 Did you discuss the facts and</p> <p>9 articles that you felt were most important</p> <p>10 to you in drawing the opinions in your</p> <p>11 report?</p> <p>12 A Yes, I did.</p> <p>13 Q There are also several articles that are</p> <p>14 cited throughout your report.</p> <p>15 In terms of your decision-making, why</p> <p>16 did you decide to cite those particular</p> <p>17 articles in your report?</p> <p>18 A The articles that I picked are the ones</p> <p>19 that, you know, I feel reflect the</p> <p>20 information the way I use it and know it.</p> <p>21 Q I'm not sure I understand.</p> <p>22 A There's very many articles. There's</p> <p>23 hundreds and hundreds. I read some of them.</p> <p>24 I don't necessarily read them all. And some</p>	<p style="text-align: right;">Page 12</p> <p>1 decision-making when you were deciding, I</p> <p>2 want to discuss this article or that</p> <p>3 article, was there any factors involved in</p> <p>4 those articles, such as patient sample size,</p> <p>5 length of follow-up, type of study that was</p> <p>6 more or less important to you in determining</p> <p>7 what to specifically discuss in the body of</p> <p>8 your report?</p> <p>9 A All of the above.</p> <p>10 Q So, patient sample size, length of</p> <p>11 follow-up --</p> <p>12 A Right.</p> <p>13 Q -- those were all factors that you</p> <p>14 considered in deciding whether or not to</p> <p>15 include those studies in the body of your</p> <p>16 report?</p> <p>17 A That is correct.</p> <p>18 Q Is the type of safety outcomes that's</p> <p>19 measured one of the selection criteria for</p> <p>20 documents that you chose to include within</p> <p>21 the body of your report?</p> <p>22 A I don't understand that question.</p> <p>23 Q Which part do you not understand? The</p> <p>24 safety outcomes part?</p>
<p style="text-align: right;">Page 11</p> <p>1 of them I use and -- some of the articles</p> <p>2 I've used here and some of them I haven't.</p> <p>3 There's no way to cite them all.</p> <p>4 Q I understand. My question is: In terms of</p> <p>5 the ones that you decided to cite, why did</p> <p>6 you choose to cite those articles in</p> <p>7 particular?</p> <p>8 A Because they were good articles, I felt.</p> <p>9 Q When you say they were good articles, what</p> <p>10 was good about them that made you decide to</p> <p>11 discuss them specifically in the body of</p> <p>12 your report?</p> <p>13 A Well, they provide information that I think</p> <p>14 is relevant.</p> <p>15 Q Is there any information that you</p> <p>16 specifically thought was more or less</p> <p>17 relevant to include within the body of your</p> <p>18 report?</p> <p>19 A I can't answer that question directly the</p> <p>20 way it's asked because it's too general.</p> <p>21 You would have to look at each article and</p> <p>22 talk about them. I can't just give one</p> <p>23 blanket statement all articles.</p> <p>24 Q Fair enough. But in terms of your</p>	<p style="text-align: right;">Page 13</p> <p>1 A Repeat the question.</p> <p>2 Q Okay. The question was: Was safety</p> <p>3 outcomes one of the selection criteria --</p> <p>4 strike that.</p> <p>5 Was measuring safety or adverse event</p> <p>6 outcomes one of the selection criteria that</p> <p>7 you used in deciding what articles to</p> <p>8 discuss within the body of your report?</p> <p>9 A I did not state it or use it the way you</p> <p>10 worded it there. I don't really know how to</p> <p>11 answer that other than that was not a</p> <p>12 specific criteria in selecting, no.</p> <p>13 Q So then, safety outcomes was not one of the</p> <p>14 selection criteria for articles that you</p> <p>15 chose to discuss within your expert report?</p> <p>16 A Safety outcome is important in the whole</p> <p>17 field, the whole study, every article,</p> <p>18 everything you do, safety outcome is the</p> <p>19 main thing. And I don't sit it down as</p> <p>20 picking articles that give certain outcomes.</p> <p>21 You read them no matter what outcome is in</p> <p>22 the article and you compare them all to get</p> <p>23 an impression of the whole picture.</p> <p>24 Q In terms of selecting articles to discuss</p>

<p style="text-align: right;">Page 14</p> <p>1 within the body of your report, did you try 2 to select the articles that were most 3 supportive of your opinions that the TVT and 4 TVT-O is relatively safe? 5 A No. My opinion comes the other way. My 6 opinion as far as safety comes from working 7 in the field for years, seeing many, many 8 patients and reading articles of all kinds 9 of all outcomes. You want to see articles 10 that show bad outcomes just as much as good 11 outcomes. 12 Q What articles that were discussed in the 13 body of your expert report did you feel show 14 bad outcomes? 15 A I can't list them right off my head. You 16 would have to put the article in front of me 17 to look at. When it comes to the slings, 18 I'm the user of them. I'm interested in 19 slings that work well. I don't have any 20 skin in this as far as what is good and what 21 is bad. I want only the good stuff. 22 Q Doctor, I'm going to mark as Exhibit No. 3 23 your reliance list to your expert report. 24 (Exhibit No. 3 Marked.)</p>	<p style="text-align: right;">Page 16</p> <p>1 much of it. I can't say that I've read all 2 of it. 3 Q So, how would I -- how would we get a list 4 of all the materials you have actually 5 reviewed and relied upon in forming your 6 opinions in this case if it's not accurately 7 reflected in Exhibit No. 3? 8 MS. VAN STEENBURGH: Object to 9 form. 10 THE WITNESS: I don't know if I 11 can produce a list of everything I read. You 12 know that's impossible. These articles here, 13 this information I'm willing to discuss 14 that's laid in front of me and willing to go 15 over it. I read a good sample of this list 16 here, and I think those articles are picked 17 well. 18 BY MR. FAES: 19 Q So, am I correct then that as we sit here 20 today, you don't have any kind of list you 21 can give me of materials that you've 22 actually reviewed and relied upon in forming 23 your opinions in this case? 24 MS. VAN STEENBURGH: Object to</p>
<p style="text-align: right;">Page 15</p> <p>1 BY MR. FAES: 2 Q And does this contain all of the materials 3 that you reviewed and relied upon in forming 4 your opinions in this case? 5 A I have reviewed some of these articles. 6 Some of them are given to me by the law firm 7 to review. I've reviewed most of them, but 8 I can't say I've reviewed every one of them. 9 Q So, the document that's in front of you 10 marked as Exhibit No. 3 was not put together 11 by you. It was put together by counsel for 12 Ethicon -- 13 A No. A hundred percent. 14 Q Let me get the whole question out. Doctor, 15 so the document marked in front of you as 16 Exhibit No. 3, was that put together by you 17 or counsel for Ethicon and 18 Johnson & Johnson? 19 A It was mostly put together by the lawyers. 20 Q Okay. And I think you testified a minute 21 ago that there were materials on this 22 reliance list that you haven't actually 23 reviewed. Is that accurate? 24 A There's a lot of material here. I have read</p>	<p style="text-align: right;">Page 17</p> <p>1 form. 2 THE WITNESS: I cannot -- 3 correct. I cannot give you everything that 4 I've read. 5 BY MR. FAES: 6 Q Now, in your expert report -- and it doesn't 7 have page numbers. I kind of went through 8 and numbered them myself, excluding -- I 9 start here (indicating) with page 1. But on 10 page number 1, which is the first page that 11 actually has, you know, the body of your 12 report at the bottom, you state that you 13 have also reviewed the plaintiffs' expert 14 reports and materials cited by plaintiffs' 15 experts. 16 Do you see that? 17 A Yes. 18 Q Is that a true statement? 19 A Yes. Well, I have not received information 20 about several plaintiffs and I have not yet 21 read them all, but I've read some. Yes, 22 they are on the desk to be read. 23 Q So, if you turn to the last page of Exhibit 24 No. 3, which is your reliance list, under</p>

<p style="text-align: right;">Page 18</p> <p>1 Expert Reports --</p> <p>2 A Right.</p> <p>3 Q -- are those all expert reports that you</p> <p>4 reviewed?</p> <p>5 A I have read Elliott, Klinge, Margolis. I</p> <p>6 have read one of these plaintiffs -- I</p> <p>7 started reading some other ones, but they</p> <p>8 were canceled. There's one of them that</p> <p>9 I've read. I read Rosenzweig.</p> <p>10 Q You read all the Rosenzweig ones?</p> <p>11 A I can't say if I read them all.</p> <p>12 Q Are there any expert reports that you</p> <p>13 reviewed and relied upon for your opinions</p> <p>14 in this case that are not listed on this --</p> <p>15 on the last page of your reliance list</p> <p>16 marked as Exhibit No. 3?</p> <p>17 A No.</p> <p>18 Q Now, it states in your expert report that</p> <p>19 you've reviewed the materials cited by</p> <p>20 plaintiffs' experts as well.</p> <p>21 Is that accurate?</p> <p>22 A Well, I assume so. I have read everything</p> <p>23 that I was given.</p> <p>24 MS. VAN STEENBURGH: To the</p>	<p style="text-align: right;">Page 20</p> <p>1 reviewed?</p> <p>2 A No.</p> <p>3 Q When you state that you've read materials</p> <p>4 cited by plaintiffs' experts, if you -- in</p> <p>5 the case where you actually reviewed that</p> <p>6 material, do you review the entire document</p> <p>7 cited by plaintiffs' experts, or do you just</p> <p>8 review part of the document?</p> <p>9 A Some of them full document and some of them</p> <p>10 part of the document.</p> <p>11 Q So, for example, Dr. Rosenzweig cites in his</p> <p>12 expert report the testimony of a particular</p> <p>13 medical director in a deposition or in trial</p> <p>14 testimony. Is it your typical practice to</p> <p>15 go and review just the section that</p> <p>16 Dr. Rosenzweig is discussing, or do you</p> <p>17 review the deposition in its entirety?</p> <p>18 A I don't have a typical practice, but</p> <p>19 whatever deposition Dr. Rosenzweig gave, one</p> <p>20 of them I read. I'm sure I haven't read it</p> <p>21 all.</p> <p>22 Q If you turn, I guess, two pages back on your</p> <p>23 reliance list marked as Exhibit No. 3,</p> <p>24 there's a list labeled "Company Witness</p>
<p style="text-align: right;">Page 19</p> <p>1 extent that some of those are articles that</p> <p>2 they've cited, I believe that he's looked at</p> <p>3 those.</p> <p>4 BY MR. FAES:</p> <p>5 Q So, I guess my question is: First of all,</p> <p>6 when you say that you've reviewed materials</p> <p>7 cited by plaintiffs' experts, are you saying</p> <p>8 that you've reviewed materials cited in the</p> <p>9 main body of the report, or are you saying</p> <p>10 that you've reviewed everything on those</p> <p>11 experts' reliance list?</p> <p>12 A I haven't reviewed everything, but I've</p> <p>13 looked at a good number of it. It's too</p> <p>14 much to have reviewed all of it. I've</p> <p>15 reviewed a good number of it, yes.</p> <p>16 Q Again, is there any list or document</p> <p>17 anywhere that would reflect what materials</p> <p>18 are cited within plaintiffs' expert reports</p> <p>19 that you've actually reviewed --</p> <p>20 A No.</p> <p>21 Q -- versus -- let me get the whole question</p> <p>22 out.</p> <p>23 -- versus materials cited in expert</p> <p>24 reports which you have not actually</p>	<p style="text-align: right;">Page 21</p> <p>1 Depositions."</p> <p>2 A Where?</p> <p>3 Q Here (indicating). It's the page where the</p> <p>4 header is "Company Witness Depositions" at</p> <p>5 the top.</p> <p>6 A (Witness reviews the document.)</p> <p>7 I have not read those yet.</p> <p>8 Q So, you haven't read any of the depositions?</p> <p>9 A No, not yet.</p> <p>10 Q Do you know why those are on your reliance</p> <p>11 list or why they were selected?</p> <p>12 A No. I was probably supposed to read them</p> <p>13 eventually. There's so much reading here, I</p> <p>14 haven't gotten to it yet.</p> <p>15 Q So, in terms of your selection for materials</p> <p>16 that review and rely upon in reaching your</p> <p>17 opinions in this case, do you generally rely</p> <p>18 on counsel for Ethicon and Johnson & Johnson</p> <p>19 to get you what you need?</p> <p>20 MS. VAN STEENBURGH: Object to</p> <p>21 form.</p> <p>22 THE WITNESS: Can you tell me</p> <p>23 what you mean with "this case"? I don't know</p> <p>24 if that's a general discussion.</p>

<p style="text-align: right;">Page 22</p> <p>1 BY MR. FAES:</p> <p>2 Q When I say "this case," I mean the general</p> <p>3 opinions in your expert report marked in</p> <p>4 front of you as Exhibit No. 2.</p> <p>5 A Well, when it comes to the slings and the</p> <p>6 patients, each one has to be looked at, you</p> <p>7 know. We have to look at the case. This is</p> <p>8 general information. I haven't read</p> <p>9 everything yet. I'm working on it. We</p> <p>10 haven't had a single case in front of me</p> <p>11 yet. It's general background information.</p> <p>12 There's many things here I've read and many</p> <p>13 things I'm still working on.</p> <p>14 Q Right. But my question is --</p> <p>15 A None of my opinions are premade. I'm still</p> <p>16 in the process of working on this.</p> <p>17 Q So, you're still in the process of working</p> <p>18 on your expert report?</p> <p>19 MS. VAN STEENBURGH: Object to</p> <p>20 form.</p> <p>21 THE WITNESS: On the literature</p> <p>22 involved and the articles. They're numerous.</p> <p>23 You can sit and read every day, all day,</p> <p>24 forever if you wanted. There's so much to</p>	<p style="text-align: right;">Page 24</p> <p>1 a few things that I've read lately. It's</p> <p>2 based on years of reading. I cannot list</p> <p>3 for you everything that's involved in that.</p> <p>4 It's many years of acquiring knowledge about</p> <p>5 the products.</p> <p>6 Q So, do you feel like you could have written</p> <p>7 this report without reviewing any new or</p> <p>8 additional materials within the last six</p> <p>9 months to a year?</p> <p>10 A No. But I have reviewed and I haven't seen</p> <p>11 any very new and different information come</p> <p>12 out lately. It is more information about</p> <p>13 the same. Different angle, different</p> <p>14 article. Nothing has been a revolutionary</p> <p>15 change that I've seen. That's the main</p> <p>16 thing I have gotten out of the reading is I</p> <p>17 haven't seen anything very new.</p> <p>18 Q Okay. Let me back up a little bit and see</p> <p>19 if I can maybe get at what I'm asking.</p> <p>20 When were you first approached to be</p> <p>21 an expert regarding the TVT and TVT-O?</p> <p>22 A I have to refer that to you. When was that?</p> <p>23 I got a call sometime -- was it in the</p> <p>24 spring or -- winter or spring.</p>
<p style="text-align: right;">Page 23</p> <p>1 read. With my schedule, I haven't read it</p> <p>2 all, but I'm still working on it.</p> <p>3 BY MR. FAES:</p> <p>4 Q I understand. My question -- I don't think</p> <p>5 I -- maybe I asked a poor question. But</p> <p>6 what I am trying to ask is: In terms of the</p> <p>7 materials that you felt you needed to review</p> <p>8 in order to form your opinions regarding the</p> <p>9 TVT and TVT-O, which is reflected in your</p> <p>10 expert report that we're here to discuss</p> <p>11 today, how did you decide what materials you</p> <p>12 needed to review and what materials you</p> <p>13 didn't need to review? What was your</p> <p>14 process?</p> <p>15 A My -- my experience and knowledge with</p> <p>16 slings go back many years. I work with them</p> <p>17 all the time. I go to conferences. I go to</p> <p>18 classes. I read articles. It's a work in</p> <p>19 progress. I have sat down and read a whole</p> <p>20 bunch of these articles that relate to this</p> <p>21 lately. I've reviewed things that I've read</p> <p>22 before. I've read a few things that I've</p> <p>23 not read before. It's a work in progress.</p> <p>24 But my opinions are not just based on</p>	<p style="text-align: right;">Page 25</p> <p>1 Q Just do the best you can, if you can,</p> <p>2 Doctor, to the best of your recollection.</p> <p>3 A I got a call asking if I would come to a</p> <p>4 meeting and talk to me about possibly doing</p> <p>5 this expert work. We had a couple meetings.</p> <p>6 It hasn't been that long ago since I started</p> <p>7 getting some material to read.</p> <p>8 Q So, was it the spring of this year, or was</p> <p>9 it the spring of last year?</p> <p>10 A No, spring of this year.</p> <p>11 Q So, sometime in the spring of 2017 --</p> <p>12 A Right.</p> <p>13 Q -- someone working for Ethicon and</p> <p>14 Johnson & Johnson approached you to</p> <p>15 potentially be a general expert witness on</p> <p>16 the TVT and TVT-O devices; is that accurate?</p> <p>17 A Yeah.</p> <p>18 Q And who is that who approached you?</p> <p>19 A Tracy.</p> <p>20 Q Who?</p> <p>21 A Tracy.</p> <p>22 MS. VAN STEENBURGH: Me.</p> <p>23 BY MR. FAES:</p> <p>24 Q Tracy. I'm sorry.</p>

<p style="text-align: right;">Page 26</p> <p>1 And have you -- I'm not sure if it's</p> <p>2 in your report or it was disclosed anywhere,</p> <p>3 but what's your hourly rate for working</p> <p>4 on --</p> <p>5 A \$500.</p> <p>6 Q Okay. And how many hours would you say</p> <p>7 you've spent working on your expert report</p> <p>8 and reliance list on this case?</p> <p>9 A I haven't submitted any invoice yet. But I</p> <p>10 would guess over the -- more than -- I don't</p> <p>11 know exactly how many hours I have spent</p> <p>12 yet. I would have to look at it.</p> <p>13 Q Have you been keeping track of those hours</p> <p>14 each month?</p> <p>15 A Yes, I have. I have it at home, but I have</p> <p>16 not submitted an invoice yet, so I haven't</p> <p>17 added it up. I can't give you an exact</p> <p>18 number.</p> <p>19 Q You haven't submitted any invoices for your</p> <p>20 work on the TVT and TVT-O case since you</p> <p>21 started working on it in about the spring of</p> <p>22 this year?</p> <p>23 A No, I have not.</p> <p>24 MR. FAES: Of course, we'll</p>	<p style="text-align: right;">Page 28</p> <p>1 (Exhibit No. 4 Marked.)</p> <p>2</p> <p>3 BY MR. FAES:</p> <p>4 Q Doctor, I'm going to hand you what's been</p> <p>5 marked as Deposition Exhibit No. 4.</p> <p>6 What is that document?</p> <p>7 A This is my CV.</p> <p>8 Q And when was this CV last updated?</p> <p>9 A It was updated recently. I updated it just</p> <p>10 recently for this situation here.</p> <p>11 Q On the last page they're just kind of</p> <p>12 dangling there, June 2015.</p> <p>13 Is that when this was last updated?</p> <p>14 A I think that is probably a misprint, because</p> <p>15 I updated this when I sent it to you. Was</p> <p>16 that a month or two ago? That June 2015</p> <p>17 probably shouldn't be there. I'm sure that</p> <p>18 was the previous update.</p> <p>19 Q But anyway, the CV marked in front of you as</p> <p>20 Exhibit No. 4, that represents your most</p> <p>21 current and updated CV or curriculum vitae;</p> <p>22 correct?</p> <p>23 A Yes.</p> <p>24 Q On your CV, I don't see that you have any</p>
<p style="text-align: right;">Page 27</p> <p>1 request that we get a copy of those invoices</p> <p>2 when they're submitted.</p> <p>3 MS. VAN STEENBURGH: Absolutely.</p> <p>4 BY MR. FAES:</p> <p>5 Q And as you sit here today, you don't have --</p> <p>6 you don't have any kind of estimate on the</p> <p>7 total number of hours you've spent so far</p> <p>8 working on the case?</p> <p>9 A No, I can't just tell you that. I would</p> <p>10 have to look it up.</p> <p>11 MS. VAN STEENBURGH: We'll</p> <p>12 submit those invoices to you.</p> <p>13 THE WITNESS: I can look it up.</p> <p>14 I don't have it in front of me.</p> <p>15 BY MR. FAES:</p> <p>16 Q For your time sitting in your deposition</p> <p>17 here today, is it the same rate, \$500 an</p> <p>18 hour?</p> <p>19 A That hasn't even been discussed, as far as I</p> <p>20 recall.</p> <p>21 Q Do you know if you have a different rate if</p> <p>22 you're called to testify at the trial?</p> <p>23 A I haven't even discussed it with the law</p> <p>24 firm, no.</p>	<p style="text-align: right;">Page 29</p> <p>1 list of any kind of peer-reviewed</p> <p>2 publications; is that correct?</p> <p>3 A Yeah. No.</p> <p>4 Q Have you written or published any articles</p> <p>5 in peer-reviewed journals or articles?</p> <p>6 A No.</p> <p>7 Q Have you written any articles that have been</p> <p>8 published elsewhere?</p> <p>9 A As an undergraduate student, I was part of a</p> <p>10 research project in chemistry and have my</p> <p>11 name on it.</p> <p>12 Q So, you haven't written anything, like, in</p> <p>13 the last five years that's been published in</p> <p>14 any kind of journals or articles at all?</p> <p>15 A That's correct.</p> <p>16 Q How much time did you spend preparing for</p> <p>17 your deposition today?</p> <p>18 A A couple days. Not full days. A couple</p> <p>19 half days.</p> <p>20 Q So, a couple half days yesterday --</p> <p>21 A Yes.</p> <p>22 Q -- and Tuesday?</p> <p>23 A No. I was operating on Tuesday. Last week.</p> <p>24 Q Okay. And how long did you prepare for each</p>

<p style="text-align: right;">Page 30</p> <p>1 day?</p> <p>2 A For --</p> <p>3 Q How much time did you spend each of those</p> <p>4 two days preparing for your deposition here</p> <p>5 today?</p> <p>6 A Yesterday, I spent three hours. And last</p> <p>7 week, I spent three hours one day and I</p> <p>8 think I spent two hours one day.</p> <p>9 Q And who did you meet with?</p> <p>10 MS. VAN STEENBURGH: Object to</p> <p>11 form.</p> <p>12 THE WITNESS: This was at home</p> <p>13 reading, going through some of these papers.</p> <p>14 I met with her, Tracy, a week and a half ago,</p> <p>15 two weeks ago. We had a two-hour meeting</p> <p>16 here.</p> <p>17 BY MR. FAES:</p> <p>18 Q So, am I correct that you are not doing any</p> <p>19 current research on any polypropylene</p> <p>20 meshes?</p> <p>21 A That is correct.</p> <p>22 Q Is it true that you've never written a</p> <p>23 peer-reviewed journal article on</p> <p>24 polypropylene mesh?</p>	<p style="text-align: right;">Page 32</p> <p>1 chemistry?</p> <p>2 A No.</p> <p>3 Q Have you ever done any bench research on</p> <p>4 polypropylene or polypropylene meshes?</p> <p>5 A No.</p> <p>6 Q Have you ever done any lab research on</p> <p>7 polypropylene or polypropylene meshes?</p> <p>8 A No.</p> <p>9 Q Have you ever done any kind of pathological</p> <p>10 analysis on any explanted polypropylene</p> <p>11 meshes?</p> <p>12 A No.</p> <p>13 Q Would you agree that you're not a</p> <p>14 biomaterials specialist?</p> <p>15 MS. VAN STEENBURGH: Object to</p> <p>16 form.</p> <p>17 THE WITNESS: That's correct.</p> <p>18 BY MR. FAES:</p> <p>19 Q Have you ever published -- strike that.</p> <p>20 Would you agree that you've never</p> <p>21 published any opinions, other than your</p> <p>22 expert report that we'll discuss in a little</p> <p>23 bit, that polypropylene does not degrade in</p> <p>24 the human body?</p>
<p style="text-align: right;">Page 31</p> <p>1 A That is correct.</p> <p>2 Q Is it correct that you've never written on</p> <p>3 the Burch procedure?</p> <p>4 A That's correct.</p> <p>5 Q You've never written any peer-reviewed</p> <p>6 journal or article on the Burch procedure?</p> <p>7 A That is correct.</p> <p>8 Q You've never written any peer-reviewed</p> <p>9 medical journal article or co-written any</p> <p>10 article on the pubovaginal sling or</p> <p>11 biological slings?</p> <p>12 A That's correct.</p> <p>13 Q Do you consider yourself an academic</p> <p>14 physician?</p> <p>15 A No.</p> <p>16 Q Would you agree that you're not an expert or</p> <p>17 you don't hold yourself out as an expert in</p> <p>18 chemical engineering?</p> <p>19 A That is correct.</p> <p>20 Q You're not an expert in pathology?</p> <p>21 A That is correct.</p> <p>22 Q You're not an expert in polymer chemistry?</p> <p>23 A That is correct.</p> <p>24 Q Do you have any background in polymer</p>	<p style="text-align: right;">Page 33</p> <p>1 A That is correct.</p> <p>2 Q Have you ever published any opinions that</p> <p>3 polypropylene does not create a foreign body</p> <p>4 response?</p> <p>5 A That is correct.</p> <p>6 Q Do you consider yourself an expert on</p> <p>7 warnings regarding medical devices?</p> <p>8 A Say that again.</p> <p>9 MS. VAN STEENBURGH: Form.</p> <p>10 BY MR. FAES:</p> <p>11 Q Do you consider yourself an expert on</p> <p>12 warnings of medical devices?</p> <p>13 A No.</p> <p>14 Q Would you agree that you're not an expert on</p> <p>15 what risk information medical devices are</p> <p>16 required to put in their IFUs, or</p> <p>17 instructions for use?</p> <p>18 A That is correct.</p> <p>19 Q Would you agree you're not an expert</p> <p>20 regarding what industry standards govern</p> <p>21 warnings on medical devices?</p> <p>22 A That is correct.</p> <p>23 Q Do you have any kind of knowledge or</p> <p>24 understanding regarding what departments of</p>

<p style="text-align: right;">Page 34</p> <p>1 a medical device company are involved in</p> <p>2 creating warnings that go in an IFU or</p> <p>3 instructions for use?</p> <p>4 A No.</p> <p>5 MS. VAN STEENBURGH: Counsel,</p> <p>6 we're not offering him an as IFU expert based</p> <p>7 on industry standard or FDA.</p> <p>8 MR. FAES: I understand.</p> <p>9 BY MR. FAES:</p> <p>10 Q Have you ever read any testimony from any</p> <p>11 Ethicon or Johnson & Johnson employees</p> <p>12 regarding Ethicon's position or policies</p> <p>13 regarding what needs to be in an IFU or</p> <p>14 instruction for use?</p> <p>15 A No, no.</p> <p>16 Q And I'm correct that you don't know what the</p> <p>17 FDA requirements are regarding warnings for</p> <p>18 medical devices?</p> <p>19 A Correct.</p> <p>20 Q Have you ever drafted an IFU or DFU for a</p> <p>21 medical device?</p> <p>22 A No.</p> <p>23 Q Have you ever worked on any kind of warnings</p> <p>24 for a medical device?</p>	<p style="text-align: right;">Page 36</p> <p>1 significant risks to doctors that come with</p> <p>2 the use of that device?</p> <p>3 MS. VAN STEENBURGH: Form,</p> <p>4 foundation.</p> <p>5 THE WITNESS: Yes.</p> <p>6 BY MR. FAES:</p> <p>7 Q Do you hold yourself out as an expert in the</p> <p>8 design of pelvic mesh products?</p> <p>9 A No.</p> <p>10 Q So, I take it, then, that you don't know</p> <p>11 what standards a manufacturer must follow in</p> <p>12 designing a mesh product like the TVT or</p> <p>13 TVT-O?</p> <p>14 A Correct.</p> <p>15 Q You'd agree that you don't know what</p> <p>16 responsibility the manufacturer holds in</p> <p>17 designing a mesh product like the TVT and</p> <p>18 TVT-O?</p> <p>19 MS. VAN STEENBURGH: Object to</p> <p>20 form.</p> <p>21 THE WITNESS: I would assume</p> <p>22 they have a responsibility to make safe</p> <p>23 products, but I can't say that I know that</p> <p>24 I -- I don't think that was a good question.</p>
<p style="text-align: right;">Page 35</p> <p>1 A No.</p> <p>2 Q Have you ever worked on any kind of warnings</p> <p>3 or instructions for use for prescription</p> <p>4 drugs?</p> <p>5 A No.</p> <p>6 Q Would you agree that physicians should be</p> <p>7 made aware of all of the significant safety</p> <p>8 risks associated with a product in the IFU</p> <p>9 or instructions for use?</p> <p>10 MS. VAN STEENBURGH: Objection</p> <p>11 to form.</p> <p>12 THE WITNESS: I do.</p> <p>13 BY MR. FAES:</p> <p>14 Q Would you agree that a manufacturer of a</p> <p>15 medical device that will be implanted in a</p> <p>16 woman's body is required to disclose all</p> <p>17 significant risks to doctors that come with</p> <p>18 the use of the device?</p> <p>19 A Ask that question again.</p> <p>20 MS. VAN STEENBURGH: Form.</p> <p>21 BY MR. FAES:</p> <p>22 Q Would you agree that a manufacturer of a</p> <p>23 medical device that will be implanted in a</p> <p>24 woman's body is required to disclose all the</p>	<p style="text-align: right;">Page 37</p> <p>1 Ask it again and I'll try.</p> <p>2 BY MR. FAES:</p> <p>3 Q So, you'd agree, then, that a medical device</p> <p>4 company has a responsibility to make safe</p> <p>5 products?</p> <p>6 A Absolutely.</p> <p>7 Q Do you have any idea how a medical device</p> <p>8 company goes about designing a medical</p> <p>9 device like the TVT or TVT-O?</p> <p>10 A No.</p> <p>11 Q You don't have any kind of idea of what</p> <p>12 experts or what kind of people are involved</p> <p>13 in designing a medical device like the TVT</p> <p>14 or TVT-O?</p> <p>15 A Some idea but no detailed information, no.</p> <p>16 Q You don't expect to offer any expert</p> <p>17 opinions regarding what type of people are</p> <p>18 involved in the design of a medical device</p> <p>19 like the TVT or TVT-O?</p> <p>20 A No.</p> <p>21 Q Do you know what a design history file is?</p> <p>22 A No.</p> <p>23 Q So, I take it, then, that you haven't</p> <p>24 reviewed the design history file for the TVT</p>

<p style="text-align: right;">Page 38</p> <p>1 or TVT-O in coming to your conclusions in 2 this case? 3 A I can't say if I reviewed it, because I 4 don't know what -- what -- 5 Q Do you know what a failure modes effects 6 analysis is? 7 A No. 8 Q Do you know what a design modes effects 9 analysis is? 10 A Technical term from a -- 11 Q I want to know if you know what that term 12 means or not. 13 A No, I don't. 14 Q To the best of your knowledge, have you ever 15 reviewed any of the failure modes effects 16 analysis, whether it be the design failure 17 modes, the process failure modes, or the 18 application failure modes effects analysis 19 for the TVT or TVT-O device? 20 A Where would I see that or find that or get 21 that? I don't -- where would that be? 22 Q So, let me back up. 23 So, my question is: As you sit here 24 today, you don't recall reviewing any of</p>	<p style="text-align: right;">Page 40</p> <p>1 in your practice today? 2 A Yes, I do. 3 Q You do the laparoscopic as opposed to the 4 open? 5 A Yes. 6 Q When's the last time you did a Burch 7 procedure? 8 A A few weeks ago. 9 Q So, since you're still performing the Burch 10 procedure, I assume that you'll agree with 11 me that the Burch procedure for the 12 treatment of stress urinary incontinence is 13 still within the standard of care? 14 A Yes, it is. 15 Q Are those the only procedures that you 16 currently perform for surgical procedures 17 for stress urinary incontinence, the 18 retropubic sling, the obturator sling and 19 the Burch procedure? 20 A Primary procedures, yes. I also do 21 paravaginal repairs, surgery for prolapse. 22 But primarily for -- 23 Q But for stress urinary incontinence -- 24 A It's the two slings and the Burch procedure</p>
<p style="text-align: right;">Page 39</p> <p>1 those things -- 2 A For the company or -- 3 Q For the TVT or the TVT-O products. 4 A Where would they be supplied? 5 Q Well, you'd have to get them from Ethicon or 6 Johnson & Johnson. 7 A No, I don't. 8 Q Is that something that you feel like you 9 should review or would want to review in 10 forming your opinions in this case? 11 A I don't have any opinion on that, because I 12 don't know what it is. I don't believe I've 13 ever seen it. 14 Q So, let's talk about your medical practice a 15 little bit. Okay? 16 A Okay. 17 Q You -- first of all, what -- back up. 18 First of all, what surgical 19 procedures do you currently perform for the 20 treatment of stress urinary incontinence? 21 A Synthetic midurethral retropubic sling, 22 synthetic midurethral obturator sling, and 23 the Burch procedure. 24 Q So, you do still perform the Burch procedure</p>	<p style="text-align: right;">Page 41</p> <p>1 are the ones I use today. 2 Q Right. So, for stress urinary incontinence, 3 the only surgical procedures that you 4 currently perform in your practice is the 5 retropubic polypropylene sling, the 6 obturator polypropylene sling, and the Burch 7 procedure; correct? 8 A That is correct. 9 Q Okay. Now, in terms of the -- so, you don't 10 currently perform any kind of sling 11 procedures with a nonpolypropylene mesh, 12 such as natural tissue or cadaver? 13 A No, not currently. 14 Q But you've done that in your practice 15 before; correct? 16 A Yes. 17 Q Would you agree that the sling procedure 18 with a piece of fascia or cadaveric tissue 19 is still within the standard of care today 20 for the treatment of stress urinary 21 incontinence? 22 A Yes. 23 Q In terms of the retropubic and obturator 24 slings that you put in in your practice</p>

<p style="text-align: right;">Page 42</p> <p>1 currently, what slings do you use?</p> <p>2 A Ethicon.</p> <p>3 Q What kind of Ethicon slings?</p> <p>4 A For retropubic, I use TVT-Exact. And for</p> <p>5 obturator, I use TVT-O.</p> <p>6 Q TVT-O?</p> <p>7 A Yes.</p> <p>8 Q So, currently, you're not using the TVT</p> <p>9 retropubic sling that's the subject -- one</p> <p>10 of the subjects of your expert report.</p> <p>11 You're using the TVT-Exact; right?</p> <p>12 A Yes.</p> <p>13 Q When did you stop using the TVT retropubic</p> <p>14 or TVT classic sling?</p> <p>15 A The minute I got the first TVT-Exact sling,</p> <p>16 I don't know what year it was, but when it</p> <p>17 came out.</p> <p>18 Q Why did you stop using the TVT retropubic or</p> <p>19 TVT classic sling when you first used the</p> <p>20 TVT-Exact?</p> <p>21 A The TVT-Exact was a newer and better model,</p> <p>22 thinner insertion instrument. It made a</p> <p>23 smaller tract.</p> <p>24 Q So, do you feel that the TVT-Exact device is</p>	<p style="text-align: right;">Page 44</p> <p>1 Q So, were you using both simultaneously, or</p> <p>2 was there a point where you switched over</p> <p>3 from the mechanically cut TVT to the</p> <p>4 laser-cut TVT exclusively?</p> <p>5 A I can't recall exactly how it went, but it</p> <p>6 probably went this way: that we used up what</p> <p>7 we had and then we went to the newer ones</p> <p>8 once they came in.</p> <p>9 Q When you say the newer ones, do you mean the</p> <p>10 laser-cut TVT retropubic?</p> <p>11 A Yes. I remember there was a switch over</p> <p>12 there.</p> <p>13 Q Now, with regard to the TVT-O device that</p> <p>14 you currently use in your practice, what</p> <p>15 version of that do you use? The</p> <p>16 mechanically cut or the laser cut?</p> <p>17 A I think all of them are laser cut now. I</p> <p>18 don't think I've seen a nonlaser cut one in</p> <p>19 a long time. I use at the moment probably</p> <p>20 99 percent retropubic sling. Occasionally</p> <p>21 will still put in an obturator but rare. I</p> <p>22 used to use obturator a lot more.</p> <p>23 Q Why has your use of TVT-O slings declined?</p> <p>24 Well, strike that.</p>
<p style="text-align: right;">Page 43</p> <p>1 safer than the TVT retropubic device?</p> <p>2 A I don't know if it's safer, but it is less</p> <p>3 invasive. The idea here is minimal invasive</p> <p>4 surgery. Smaller cuts and smaller sticks is</p> <p>5 usually better.</p> <p>6 Q Before you switched -- strike that.</p> <p>7 You do have an understanding that the</p> <p>8 TVT-Exact is only offered in laser-cut mesh</p> <p>9 and isn't offered in mechanical-cut mesh;</p> <p>10 correct?</p> <p>11 A Yes, I do.</p> <p>12 Q And you had that understanding before --</p> <p>13 strike that.</p> <p>14 You actually had that understanding</p> <p>15 when you switched to the TVT-Exact, that it</p> <p>16 was only offered in the laser-cut mesh</p> <p>17 configuration; is that correct?</p> <p>18 A That is correct.</p> <p>19 Q Before you switched from the TVT retropubic</p> <p>20 to the TVT-Exact, what version of the TVT</p> <p>21 retropubic were you using? Were you using</p> <p>22 the laser cut or mechanical cut or both or</p> <p>23 do you not know?</p> <p>24 A Both.</p>	<p style="text-align: right;">Page 45</p> <p>1 Let me first ask you: So, you would</p> <p>2 agree with me that currently, the TVT</p> <p>3 retropubic is your sling of choice for</p> <p>4 stress urinary incontinence; right? Or the</p> <p>5 TVT-Exact.</p> <p>6 A For me, it is, right.</p> <p>7 Q Yes. And not the obturator.</p> <p>8 A That's correct.</p> <p>9 Q And there was a time where you used to put</p> <p>10 in more of the TVT-Os in your practice;</p> <p>11 right?</p> <p>12 A That is correct, yes.</p> <p>13 Q Why has your use of the TVT-O declined in</p> <p>14 favor of a retropubic approach sling?</p> <p>15 A Why do I use the retropubic over the</p> <p>16 obturator?</p> <p>17 Q Yes. Why is that your sling of choice?</p> <p>18 A Several reasons. One reason is the way the</p> <p>19 sling sits, it's easier to get the obturator</p> <p>20 too loose and the retropubic sling is</p> <p>21 sitting different in the body and it causes</p> <p>22 a little bit better support. I think</p> <p>23 there's better long-term results with the</p> <p>24 retropubic sling. Some studies say they're</p>

<p style="text-align: right;">Page 46</p> <p>1 the same. There's more studies -- I think 2 the general feeling in the field is that the 3 retropubic is a little sturdier sling and it 4 has better long-term results. It also can 5 work for intrinsic sphincter defect while 6 the obturator -- personally, I don't think 7 it works as well for that problem. And many 8 of the patients have mixed incontinence. 9 Another thing is, the insertion of 10 the sling is so much up to the -- it's the 11 surgeon and the hands and it is a judgment, 12 how tight you put the sling. And if you 13 do -- if you use one kind of sling, it's 14 easier to become consistent when it comes to 15 how tight you put it. If you go from 16 different slings -- they all have to be 17 tightened a little bit different and it's 18 easier to -- I think you get better results 19 if you stick with one sling. That's been my 20 experience. 21 Q So, you feel that the TVT retropubic sling 22 has better results than the TVT-O slings? 23 A I think for a person that does the TVT all 24 the time, if you choose to do that, you get</p>	<p style="text-align: right;">Page 48</p> <p>1 and to have her dry forever, if you could. 2 I think the TVT-Exact or retropubic sling is 3 a better sling. 4 Q Do you feel that the TVT retropubic sling 5 has a lower rate of complications than the 6 TVT-O sling? 7 A No, I wouldn't say that. Complications are 8 related to the insertion and I think if you 9 do many of them and if you do -- you learn 10 how to do it right and the complication rate 11 is very low in both of them if you do enough 12 of them and get experience with them. I 13 think if you focus on one sling rather than 14 two, it's even better. 15 Q Do you feel like there's no difference 16 between the complication rates between the 17 TVT and the TVT-O? 18 A They're different because they go in 19 different parts of the body. One goes 20 behind the pubic bone, almost in the pelvis, 21 so to speak. The other one goes up in the 22 groin. There's more leg pain with the 23 obturator sling. And the retropubic sling, 24 I would say there's less pain, but there can</p>
<p style="text-align: right;">Page 47</p> <p>1 really good at putting it in and tensioning 2 it right. You can tension a sling three 3 ways: too tight, too loose, or just right. 4 Every patient wants it just right, but when 5 they're sleeping under anesthesia and all 6 the muscles are relaxed and it looks good 7 and then you stand up when you wake up, 8 muscles tension and the whole thing is 9 different and it may be too tight or too 10 loose. 11 I think it's a very, very fine line 12 to get it adjusted right. If you stick with 13 one sling, it's easier to be consistent than 14 if you switch between slings. 15 I also think the body of the 16 literature pretty much states that the 17 TVT -- or the retropubic sling in the 18 long-term is a better sling. I see fewer 19 patients come back leaking after a 20 retropubic sling than a TVT-O sling. 21 Q So, do you feel that the TVT sling overall 22 is more efficacious or has better cure rates 23 than the TVT-O sling? 24 A Yes. The goal is to make the patient dry</p>	<p style="text-align: right;">Page 49</p> <p>1 be other complications if you don't do it 2 right. 3 I would say the retropubic is more 4 invasive, but the obturator causes more -- 5 even though it's less invasive, it causes 6 more leg pain. 7 Q So, you'd agree with me that sometimes a 8 surgery, even though it's more invasive, may 9 have less complications and less pain? 10 A That is correct. 11 Q Earlier, we were talking about your use of 12 the TVT obturator device and currently, you 13 only use laser-cut mesh; right? Laser-cut 14 mesh for -- 15 A As far as I know, I think all the mesh now 16 is laser cut. 17 Q Right. That's what I wanted to follow up 18 on. 19 A Yes, yes. 20 Q Is it your belief that the mechanically cut 21 mesh for the TVT-O is no longer available, 22 or is it just no longer available in the 23 facilities where you practice? 24 A I can't answer that. I don't know.</p>

<p style="text-align: right;">Page 50</p> <p>1 Q So, you just don't know one way or the 2 other?</p> <p>3 A No.</p> <p>4 Q But as you sit here today, you believe that 5 the TVT laser-cut mesh is what you use 6 exclusively when you do the TVT-O procedure?</p> <p>7 A That's correct.</p> <p>8 Q Do you believe that the TVT-O laser-cut mesh 9 allows the mesh to lie flatter beneath the 10 urethra than the mechanically cut TVT-O 11 mesh?</p> <p>12 A I don't think it makes much difference if 13 you put it in right. The laser cut is a 14 little bit more tolerant when it comes to 15 pulling it when adjusting it. The nonlaser 16 cut, it takes very little to overstretch it 17 when you adjust it. It's supposed to be 18 adjusted inside the sleeve. And if you tug 19 on the sling itself, which I don't think you 20 should do, the laser cut tolerates a little 21 bit more before it frays. But if you do it 22 right, it shouldn't matter, because you 23 shouldn't pull on the sleeve.</p> <p>24 Q Do you feel that the laser-cut mesh of the</p>	<p style="text-align: right;">Page 52</p> <p>1 ruin them. But the laser cut may tolerate a 2 little bit more adjustment.</p> <p>3 Q Do you recall actually -- well, strike that. 4 Let me back up.</p> <p>5 What hospitals do you currently have 6 privileges to practice in?</p> <p>7 A I have at all the HealthEast hospitals. 8 They just sold out to Fairview so now 9 they're going to be called Fairview 10 Hospitals. There's three of them that I 11 operate at: St. John's, St. Joseph's, and 12 Woodbury. And United Hospital. And then 13 multiple surgery centers. But I go mostly 14 to St. John's and United, because they have 15 robots and I do a lot of robot surgery, so I 16 focus on those two places.</p> <p>17 Q What percentage of your slings would you say 18 is obturator slings? Would you say less 19 than 2 percent?</p> <p>20 A Now it's less than 2 percent.</p> <p>21 Q When you do opt to use an obturator sling as 22 opposed to a retropubic sling, why do you 23 make that choice? Is there a certain set of 24 patients that you feel that the obturator</p>
<p style="text-align: right;">Page 51</p> <p>1 TVT-O prevents banding of the mesh better 2 than the mechanically cut mesh of the TVT-O?</p> <p>3 MS. VAN STEENBURGH: Object to 4 form.</p> <p>5 THE WITNESS: I think it does. 6 But the point is that the mesh doesn't bend 7 itself. It's the surgeon pulling on it. If 8 you put it in and you pull the sleeve off and 9 you think "Maybe I should have it a little 10 tighter, like two millimeters," and you try 11 to pull on it, that's when roping and bending 12 comes in.</p> <p>13 BY MR. FAES:</p> <p>14 Q Do you feel like you have to tension the 15 mesh differently between a laser-cut TVT-O 16 and the mechanically cut TVT-O?</p> <p>17 A I don't think so. I think -- you set them 18 the same way, but one is more forgiving than 19 the other if you tug a little bit on it. I 20 think that was the improvement with the 21 laser cut. It's a little -- it's kind of 22 like some eggs break easier than others but 23 they all break if you drop them.</p> <p>24 If you tug on either one of them, you</p>	<p style="text-align: right;">Page 53</p> <p>1 sling is a better option for?</p> <p>2 A Yeah. There are some patients that have had 3 surgeries that set them up for -- it would 4 be more riskier to put it in retropubic, so, 5 in order to stay out of the abdomen, I go 6 transobturator.</p> <p>7 Q Have you used the TVT Abbrevio product 8 before?</p> <p>9 A Yes. That's the one that -- yes, I have.</p> <p>10 Q And you know that's a product manufactured 11 by Ethicon and Johnson & Johnson; right?</p> <p>12 A I believe so.</p> <p>13 Q And how many times did you use the TVT 14 Abbrevio product?</p> <p>15 A I can't recall.</p> <p>16 Q Why is it that you used the laser-cut TVT-O 17 product as opposed to the Abbrevio product 18 when you have a patient that you're 19 implanting using the obturator approach?</p> <p>20 MS. VAN STEENBURGH: I think 21 we're getting a little far afield.</p> <p>22 THE WITNESS: Well, first of 23 all, I don't make a choice. I use whichever 24 TVT-O we have. You don't get to make</p>

<p style="text-align: right;">Page 54</p> <p>1 choices. That goes through the committees 2 and the hospital. They buy one kind. Right 3 now, I'm using almost exclusively retropubic 4 slings. I can still use an obturator if I 5 don't want to go in the belly, if I want to 6 just be outside the body. And what slings 7 they have on the shelf right now, I can't 8 tell you. I would have to call the hospital 9 and ask them.</p> <p>10 BY MR. FAES:</p> <p>11 Q So, is it your testimony that you don't have 12 a choice about what slings to put in your --</p> <p>13 A I don't know what they have, because I 14 haven't used it lately, whether it's Abbrevio 15 or a full-length sling. The Abbrevio has a 16 suture at the end, so there's less sling 17 material that goes into the body. It's a 18 shorter sling.</p> <p>19 Q But you'd agree that if there's a medical 20 device that you want to use, such as the TVT 21 Abbrevio, you can go to the hospital and 22 actually request that they make that product 23 available; correct?</p> <p>24 A Yes. But it's not an easy process. It's a</p>	<p style="text-align: right;">Page 56</p> <p>1 version of the same, pretty much.</p> <p>2 Q So, when was it that you -- well, strike 3 that.</p> <p>4 First, when was it during your career 5 that you first implanted your -- I'm asking 6 a bad question.</p> <p>7 When was it that you first implanted 8 a polypropylene midurethral sling in your 9 career?</p> <p>10 A It was early, but I can't recall exactly. 11 Did we talk about that once? I can't -- I 12 can't -- I don't have a log of it. Some 13 reason why I -- I know I went to Milwaukee 14 and observed Miller -- Dr. Miller -- do 15 slings. It was early on when the slings had 16 come on the market.</p> <p>17 MS. VAN STEENBURGH: Okay. 18 Hold on.</p> <p>19 THE WITNESS: I don't know a 20 year.</p> <p>21 MS. VAN STEENBURGH: Before 22 going any further, I see you're going to 23 switch subjects, do you mind --</p> <p>24 MR. FAES: Oh, sure, sure.</p>
<p style="text-align: right;">Page 55</p> <p>1 long process and I may not get it.</p> <p>2 Q Right. Do you recall doing that 3 specifically for the TVT Abbrevio?</p> <p>4 A No. I haven't needed it. I believe it is 5 available in the hospital. It's been awhile 6 since I used it. I don't know which model 7 they have on the shelf. Either one works.</p> <p>8 Q So, as you sit here today, you don't recall 9 ever signing a document or a form requesting 10 one of your hospitals that you practice in 11 make the TVT Abbrevio available?</p> <p>12 A I haven't had a need for it. I haven't had 13 a need to fill out anything for it because 14 they do -- last time I asked, they did have 15 a TVT and it was an Abbrevio. What they have 16 today, I don't know, because I haven't used 17 it for a while.</p> <p>18 Q Do you recall when the TVT-Exact became 19 available that you requested that one of 20 your hospitals make that available, as 21 opposed to using the TVT retropubic?</p> <p>22 A Yes, I remember that. But I did not have to 23 fill out anything. It was just we switched 24 from one to the other. It was just a newer</p>	<p style="text-align: right;">Page 57</p> <p>1 Let's go off the record.</p> <p>2 (Recess began - 9:59 a.m.) 3 (Recess ended - 10:04 a.m.)</p> <p>4 BY MR. FAES:</p> <p>5 Q Doctor, we're back on the record after a 6 short break.</p> <p>7 Are you ready to proceed?</p> <p>8 A Yes, I am.</p> <p>9 Q Before we went on break, we were talking 10 about your use of polypropylene midurethral 11 slings and you said you think you first used 12 it about when it first came on the market.</p> <p>13 Do you think that would have been 14 1999 or 2000?</p> <p>15 A I cannot give you the year. It was early in 16 my career, but I can't recall when.</p> <p>17 Q Do you recall what the first polypropylene 18 sling was? Was it the Ethicon TVT or was it 19 something else?</p> <p>20 A Ethicon TVT.</p> <p>21 Q Have you used any other polypropylene 22 midurethral slings for stress urinary 23 incontinence other than the TVT, TVT-O, 24 TVT-Exact and Abbrevio?</p>

<p style="text-align: right;">Page 58</p> <p>1 A Yes, I have.</p> <p>2 Q What else have you used?</p> <p>3 A I have used AMS mini sling and I have used</p> <p>4 Coloplast mini sling.</p> <p>5 Q Any others?</p> <p>6 A Not that I can recall.</p> <p>7 Q Never used a Bard Align or Ajust sling?</p> <p>8 A Not that I recall.</p> <p>9 Q Never used a Boston Scientific sling:</p> <p>10 Obtryx, Solyx or --</p> <p>11 A No.</p> <p>12 Q But you do believe you used the AMS MiniArc</p> <p>13 sling and the Coloplast Aris mini sling?</p> <p>14 A I have.</p> <p>15 Q When did you use those?</p> <p>16 A Some years ago.</p> <p>17 Q Why did you stop using them?</p> <p>18 A I just tried them on a few patients.</p> <p>19 Q And how was the results with those?</p> <p>20 A I can't recall.</p> <p>21 Q Have you ever used Ethicon's TVT Secur</p> <p>22 device?</p> <p>23 A Yes.</p> <p>24 Q And how many times did you use that?</p>	<p style="text-align: right;">Page 60</p> <p>1 polypropylene midurethral slings than you're</p> <p>2 currently doing?</p> <p>3 A No.</p> <p>4 Q So, would you say the amount that you do has</p> <p>5 remained fairly consistent over the course</p> <p>6 of your career since you've been using it?</p> <p>7 A Yeah.</p> <p>8 Q What percentage of your practice is treating</p> <p>9 women as opposed to men?</p> <p>10 A A hundred percent.</p> <p>11 Q Okay. How many times a year would you say</p> <p>12 that you currently do mesh removal or</p> <p>13 excision procedures?</p> <p>14 A I can't give you an exact number.</p> <p>15 Q What's your best estimate of how many mesh</p> <p>16 removal or excision procedures you're</p> <p>17 currently performing a year?</p> <p>18 A I do some, but I can't give you an exact</p> <p>19 number.</p> <p>20 Q Do you know if it's more or less than 20 a</p> <p>21 year, on average, currently?</p> <p>22 A Probably less.</p> <p>23 Q Do you know how many polypropylene</p> <p>24 midurethral slings you've implanted over the</p>
<p style="text-align: right;">Page 59</p> <p>1 A Three.</p> <p>2 Q Why did you stop using that?</p> <p>3 A Didn't like inserting it. I didn't like it.</p> <p>4 I didn't like the feel of inserting it.</p> <p>5 Q Did you feel like the results were good, in</p> <p>6 terms of safety and efficacy, with that</p> <p>7 device, or do you have an opinion?</p> <p>8 A I have no opinion on that.</p> <p>9 Q How many days a week are you currently in</p> <p>10 surgery?</p> <p>11 A Two full days. Sometimes more.</p> <p>12 Q And how many polypropylene midurethral</p> <p>13 slings a year would you say that you</p> <p>14 currently implant in your practice?</p> <p>15 MS. VAN STEENBURGH: Did you</p> <p>16 say per year?</p> <p>17 MR. FAES: Yes.</p> <p>18 THE WITNESS: I do anywhere</p> <p>19 from zero to five a week.</p> <p>20 BY MR. FAES:</p> <p>21 Q So, you'd say that approximately 150 to 250</p> <p>22 a year?</p> <p>23 A Whatever it adds up to, yeah.</p> <p>24 Q Was there a time when you did more</p>	<p style="text-align: right;">Page 61</p> <p>1 course of your career?</p> <p>2 A No.</p> <p>3 Q Do you know how many meshes you've removed</p> <p>4 over the course of your career?</p> <p>5 A No.</p> <p>6 Q Do you currently use any meshes for the</p> <p>7 treatment of pelvic organ prolapse?</p> <p>8 A Yes.</p> <p>9 Q What meshes do you currently use for the</p> <p>10 treatment of pelvic organ prolapse?</p> <p>11 A Coloplast Y-Mesh.</p> <p>12 Q Is that the Restorelle?</p> <p>13 A Yes.</p> <p>14 Q But you've used the Ethicon Artisyn Y mesh</p> <p>15 in the past; correct?</p> <p>16 A I've tried it, yeah.</p> <p>17 Q Have you tried it in actual live patients?</p> <p>18 A Yes, I have.</p> <p>19 Q Okay. How many times did you try it in</p> <p>20 actual live patients?</p> <p>21 A I don't recall.</p> <p>22 Q And you've also used the Prolene Soft mesh</p> <p>23 during the course of your career, right, for</p> <p>24 pelvic organ prolapse?</p>

<p style="text-align: right;">Page 62</p> <p>1 A I can't recall that.</p> <p>2 Q We'll take a look at something a little bit</p> <p>3 later, but as you sit here today, can you</p> <p>4 recall whether or not you've ever used the</p> <p>5 Prolene Soft mesh in your practice for the</p> <p>6 repair of pelvic organ prolapse?</p> <p>7 A I can't remember.</p> <p>8 Q Do you know whether or not that's made from</p> <p>9 the same material as the TVT or not?</p> <p>10 A I don't know anything about it.</p> <p>11 Q Okay. But you have used the Prolift and the</p> <p>12 Prolift+M in your practice before; right?</p> <p>13 A Yes.</p> <p>14 Q Do you know whether the Prolift is made from</p> <p>15 the Gynemesh PS mesh?</p> <p>16 A I think it is. I can't recall. It's been</p> <p>17 awhile.</p> <p>18 Q Do you know whether the Prolift is made from</p> <p>19 Prolene?</p> <p>20 A Yes.</p> <p>21 Q Okay. Are there any other meshes that</p> <p>22 you've used for pelvic organ prolapse during</p> <p>23 the course of your career?</p> <p>24 A I can't recall that.</p>	<p style="text-align: right;">Page 64</p> <p>1 MR. FAES: Let's have the court</p> <p>2 reporter read back the actual question,</p> <p>3 please.</p> <p>4 (The record was read as requested.)</p> <p>5 BY MR. FAES:</p> <p>6 Q And that mesh I am referring to is the</p> <p>7 Restorelle.</p> <p>8 A I've been happy with the Restorelle. I have</p> <p>9 no reason to look for something else.</p> <p>10 Q What percentage of your practice would you</p> <p>11 say is treating mesh complications or</p> <p>12 complications from mesh?</p> <p>13 A I can't answer that.</p> <p>14 Q You don't know if it's more or less than 10</p> <p>15 percent?</p> <p>16 MS. VAN STEENBURGH: Object to</p> <p>17 form.</p> <p>18 THE WITNESS: Less than 10</p> <p>19 percent. Oh, yeah. Less than 10 percent.</p> <p>20 BY MR. FAES:</p> <p>21 Q Now, as it's stated in your expert report,</p> <p>22 before you became a -- well, strike that.</p> <p>23 First of all, prior to being</p> <p>24 contacted by counsel for Ethicon and</p>
<p style="text-align: right;">Page 63</p> <p>1 Q But currently, the Coloplast Y-Mesh or the</p> <p>2 Restorelle is the only surgical mesh you use</p> <p>3 for the treatment of pelvic organ prolapse;</p> <p>4 is that accurate?</p> <p>5 A Correct.</p> <p>6 Q Why do you use that mesh as opposed to a</p> <p>7 different mesh such as the Ethicon Artisyn</p> <p>8 or the Ethicon Prolene Soft?</p> <p>9 MS. VAN STEENBURGH: Counsel,</p> <p>10 we're here for a general deposition on TVT</p> <p>11 and TVT-O and not --</p> <p>12 MR. FAES: Your objection's</p> <p>13 noted.</p> <p>14 MS. VAN STEENBURGH: Well, at</p> <p>15 some point, we're going to have to move on.</p> <p>16 MR. FAES: I disagree.</p> <p>17 BY MR. FAES:</p> <p>18 Q You can answer, Doctor, if you know.</p> <p>19 THE WITNESS: Ask the question</p> <p>20 again.</p> <p>21 MR. FAES: Can we have the</p> <p>22 court reporter read back the last question?</p> <p>23 MS. VAN STEENBURGH: Why do you</p> <p>24 use the Restorelle?</p>	<p style="text-align: right;">Page 65</p> <p>1 Johnson & Johnson in the spring of this</p> <p>2 year, have you ever worked as a litigation</p> <p>3 consultant for Ethicon and</p> <p>4 Johnson & Johnson?</p> <p>5 A No.</p> <p>6 Q Are you currently a litigation consultant</p> <p>7 for any other mesh companies?</p> <p>8 A No.</p> <p>9 Q Have you ever been an expert witness before</p> <p>10 in any case?</p> <p>11 A No.</p> <p>12 Q So, you've never -- this is your first time</p> <p>13 ever doing any kind of expert work; is that</p> <p>14 accurate?</p> <p>15 A Yes.</p> <p>16 Q Now, before you became a litigation</p> <p>17 consultant for Ethicon and Johnson &</p> <p>18 Johnson, you were a consultant or preceptor</p> <p>19 for Ethicon and Johnson & Johnson; correct?</p> <p>20 A Yes.</p> <p>21 Q When was it that you first became a</p> <p>22 consultant for Ethicon and</p> <p>23 Johnson & Johnson?</p> <p>24 A I can't recall.</p>

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<p>1 (Exhibit No. 5 Marked.)</p> <p>2</p> <p>3 BY MR. FAES:</p> <p>4 Q I'm going to hand you what's been marked as</p> <p>5 Exhibit No. 5 to your deposition. And this</p> <p>6 is an e-mail dated April 10th of 2005, and</p> <p>7 it's from a Scott Prefer at Ethicon. And if</p> <p>8 you look down, it states that, "I talked</p> <p>9 with Dr. Mjanger, a new TVT-O user and he is</p> <p>10 interested in single-event training</p> <p>11 contracts. He has five surgeons lined up to</p> <p>12 train in St. Paul and I think we should</p> <p>13 compensate him for his training efforts on</p> <p>14 the TVT and TVT-O. Can we pay him \$500 per</p> <p>15 event? He has a lot of credibility with</p> <p>16 many of the doctors in the St. Paul area.</p> <p>17 He is also very interested in obtaining</p> <p>18 Prolift training when we open it up to more</p> <p>19 surgeons."</p> <p>20 Do you see that?</p> <p>21 A Yes, I do.</p> <p>22 Q Does this refresh your recollection at all</p> <p>23 that approximately in April of 2005, you</p> <p>24 were first approached by Ethicon and</p>	<p>1 file that Ethicon and Johnson & Johnson</p> <p>2 keeps regarding consulting contracts it has</p> <p>3 with you. Okay?</p> <p>4 A Yeah.</p> <p>5 Q And it looks like the first page of this</p> <p>6 document is a one-time preceptorship</p> <p>7 agreement, and it looks like it's dated --</p> <p>8 at the top, it looks like it's dated April</p> <p>9 10th of 2006. And the first date of the</p> <p>10 event that you're supposed to work at is on</p> <p>11 a cadaver lab on May 12th of 2006.</p> <p>12 Do you see that on the first page?</p> <p>13 A Yes.</p> <p>14 Q And you were to be paid \$1500 for that</p> <p>15 event?</p> <p>16 A Yes, I see that.</p> <p>17 Q Do you recall that this was -- would have</p> <p>18 been the first time that you signed a</p> <p>19 consulting contract with Ethicon and</p> <p>20 Johnson & Johnson?</p> <p>21 A No, I don't recall that.</p> <p>22 Q Do you have any reason to believe that you</p> <p>23 didn't sign this contract with Ethicon and</p> <p>24 Johnson & Johnson --</p>
Page 67	Page 69
<p>1 Johnson & Johnson to be a consultant with</p> <p>2 them regarding the TVT and TVT-O?</p> <p>3 A Probably correct, yeah, sure.</p> <p>4 Q Okay. And you ultimately have signed</p> <p>5 consulting contracts with them over the</p> <p>6 years; right?</p> <p>7 A Yes, yes.</p> <p>8 Q Do you remember when the first consulting</p> <p>9 contract that you signed with them was?</p> <p>10 A No.</p> <p>11 (Exhibit No. 6 Marked.)</p> <p>12</p> <p>13 BY MR. FAES:</p> <p>14 Q I'm going to hand you what's been marked as</p> <p>15 Exhibit No. 6 to your deposition. I</p> <p>16 apologize, Doctor. I'm glad you have your</p> <p>17 reading glasses there, Doctor. I apologize</p> <p>18 for the small print. This is the way the</p> <p>19 document was produced by the company to us.</p> <p>20 MS. VAN STEENBURGH: Then I</p> <p>21 apologize on behalf of the company if it was</p> <p>22 produced in that small of print, but okay.</p> <p>23 BY MR. FAES:</p> <p>24 Q So, I'll represent to you that this is a</p>	<p>1 A No.</p> <p>2 Q -- in April of 2006?</p> <p>3 A No. Johnson & Johnson.</p> <p>4 Q If I can have you turn in this document to</p> <p>5 the Bates number ending in '5021.</p> <p>6 A (Complying.)</p> <p>7 Q And this is an ongoing preceptorship</p> <p>8 agreement dated November 5th of 2006.</p> <p>9 Do you see that on the first page?</p> <p>10 A Yes.</p> <p>11 Q And if you see down in paragraph three, it</p> <p>12 states that the amount of this contract is</p> <p>13 not to exceed \$20,000.</p> <p>14 Do you see that?</p> <p>15 A Right.</p> <p>16 Q And if you turn ending in '5026. Again, I</p> <p>17 apologize. The copy on this is terrible,</p> <p>18 but it does appear that this was signed by</p> <p>19 you.</p> <p>20 A I can't tell.</p> <p>21 Q Do you have any reason to believe that's not</p> <p>22 your signature here and you didn't sign this</p> <p>23 contract in 2006?</p> <p>24 A No.</p>

<p style="text-align: right;">Page 70</p> <p>1 Q So, you'd agree that after signing -- it</p> <p>2 appears that after signing a one-time</p> <p>3 preceptorship agreement in April of 2006,</p> <p>4 you then signed an ongoing preceptorship</p> <p>5 agreement in November of 2006 with a maximum</p> <p>6 value of \$20,000; correct?</p> <p>7 MS. VAN STEENBURGH: Object to</p> <p>8 form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. FAES:</p> <p>11 Q If I can have you turn on this document to</p> <p>12 the page ending in '5032, and this</p> <p>13 appears -- tell me when you're there.</p> <p>14 A Yes.</p> <p>15 Q This appears to be another consulting</p> <p>16 contract between you and Ethicon and</p> <p>17 Johnson & Johnson, and it looks like the</p> <p>18 date at the top is June 6th of 2008.</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q And if you turn to the page ending in '5037,</p> <p>22 again, the copy is not great, but does that</p> <p>23 appear to be your signature there on this</p> <p>24 contract?</p>	<p style="text-align: right;">Page 72</p> <p>1 recall any of these papers. But yes, I see</p> <p>2 it here.</p> <p>3 BY MR. FAES:</p> <p>4 Q Did you have an understanding, when you were</p> <p>5 a consultant for Ethicon and Johnson &</p> <p>6 Johnson, that any representations you made</p> <p>7 regarding the safety of its products needed</p> <p>8 to be reviewed and approved in advance by</p> <p>9 the company?</p> <p>10 MS. VAN STEENBURGH: Object to</p> <p>11 form.</p> <p>12 THE WITNESS: I don't recall</p> <p>13 that at all.</p> <p>14 BY MR. FAES:</p> <p>15 Q If you turn to page '5038 of this document,</p> <p>16 this appears to be an Exhibit A to your 2008</p> <p>17 contract that lists services and fees.</p> <p>18 A (Witness reviews the document.)</p> <p>19 Yes.</p> <p>20 Q And actually, can you turn to the next page</p> <p>21 ending in '5039.</p> <p>22 A (Complying.)</p> <p>23 Q And if you look under the last paragraph</p> <p>24 there, it states that "The parties agree</p>
<p style="text-align: right;">Page 71</p> <p>1 A Yes.</p> <p>2 Q If I can have you turn back on the contract</p> <p>3 to the page ending in '5034, I want to</p> <p>4 direct your attention to paragraph 12. And</p> <p>5 if you look about three-quarters of the way</p> <p>6 down in that paragraph, it states that "You</p> <p>7 shall not make any representation relating</p> <p>8 to the company's products or to the</p> <p>9 company's clinical outcomes unless such</p> <p>10 representations have been reviewed and</p> <p>11 approved in advance by the company."</p> <p>12 Do you see that?</p> <p>13 A Yes.</p> <p>14 Q Is that one of the terms that you agreed to</p> <p>15 when you were a consultant for Ethicon and</p> <p>16 Johnson & Johnson, that any representations</p> <p>17 that you made regarding the safety or</p> <p>18 efficacy of the TVT or TVT-O had to be</p> <p>19 reviewed and approved in advance by the</p> <p>20 company?</p> <p>21 MS. VAN STEENBURGH: Object to</p> <p>22 form.</p> <p>23 THE WITNESS: I see the same</p> <p>24 issue here. It is on here, but I can't</p>	<p style="text-align: right;">Page 73</p> <p>1 that the compensation to be paid to the</p> <p>2 consultant," which would be you, "is not to</p> <p>3 exceed \$30,000 per year"; correct?</p> <p>4 A Yes.</p> <p>5 Q So, you'd agree that in 2008, you had a</p> <p>6 consulting contract with Ethicon and Johnson</p> <p>7 & Johnson that was worth up to \$30,000 a</p> <p>8 year; correct?</p> <p>9 MS. VAN STEENBURGH: Object to</p> <p>10 form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. FAES:</p> <p>13 Q If you look under Section 8, "Other," it has</p> <p>14 a description of services. And we're still</p> <p>15 on the page ending on '5039.</p> <p>16 A Yes. Yes. What's the question?</p> <p>17 Q The question here is under the description</p> <p>18 of services, it states that the service --</p> <p>19 at least some of the services to be</p> <p>20 performed are "Annual Summit and Forum</p> <p>21 meetings to provide consulting inputs to</p> <p>22 improve education and effectiveness of the</p> <p>23 clinical education programs" --</p> <p>24 MS. VAN STEENBURGH: No, "of</p>

<p style="text-align: right;">Page 74</p> <p>1 the professional." He was reading from here</p> <p>2 (indicating). I think he just misread that.</p> <p>3 Sorry. Can you just start again?</p> <p>4 MR. FAES: Sure.</p> <p>5 BY MR. FAES:</p> <p>6 Q So, we're under paragraph 8 of Exhibit No.</p> <p>7 6 --</p> <p>8 MS. VAN STEENBURGH: '5039?</p> <p>9 MR. FAES: Right.</p> <p>10 BY MR. FAES:</p> <p>11 Q Description of the services in your contract</p> <p>12 is "Annual Summit and Forum meetings to</p> <p>13 provide consulting inputs to improve</p> <p>14 education in the effectiveness of the</p> <p>15 professional education programs. Also will</p> <p>16 include discussions of clinical and market</p> <p>17 developments regarding products."</p> <p>18 Do you see that?</p> <p>19 A I see that, yeah.</p> <p>20 Q So, were those part of the services that you</p> <p>21 provided to Ethicon and Johnson & Johnson as</p> <p>22 a consultant in 2008?</p> <p>23 A I don't think I ever went to summits. I</p> <p>24 know there was a request, but I don't think</p>	<p style="text-align: right;">Page 76</p> <p>1 services for Ethicon and Johnson & Johnson</p> <p>2 under this contract in 2008, such as</p> <p>3 precepting or teaching TVT or TVT-O events?</p> <p>4 A I can't remember years. I know over a</p> <p>5 number of years, I did precepting in the</p> <p>6 operating room in St. Paul, in my own</p> <p>7 operating room.</p> <p>8 Q How many times would you say you've done</p> <p>9 precepting for Ethicon and Johnson & Johnson</p> <p>10 between 2006 and the present?</p> <p>11 A I can't give you a number, but I can tell</p> <p>12 you it was mostly local doctors that were</p> <p>13 learning the slings and they would come in</p> <p>14 and watch me do it. And I would sometimes</p> <p>15 watch them do their first. That's all I can</p> <p>16 remember I did for Ethicon, plus that trip</p> <p>17 to Florida.</p> <p>18 Q Okay. And actually, if you -- sorry. Let</p> <p>19 me know when you're done.</p> <p>20 A That's all I have. Yeah.</p> <p>21 Q Okay. And actually, if you turn a page</p> <p>22 forward in the same contract to the page</p> <p>23 ending in '5038, under paragraph 4, it also</p> <p>24 states, under Preceptor Surgical Training</p>
<p style="text-align: right;">Page 75</p> <p>1 I ever went, if I remember correctly.</p> <p>2 Q You don't think you went to any summits in</p> <p>3 2008?</p> <p>4 A No, no.</p> <p>5 Q Do you think you went to any summits ever</p> <p>6 for Ethicon and Johnson & Johnson?</p> <p>7 A No.</p> <p>8 Q You don't recall going to a summit in 2012</p> <p>9 to develop -- to evaluate the Artisyn</p> <p>10 product?</p> <p>11 A What's the Artisyn product?</p> <p>12 Q The Y mesh.</p> <p>13 A I went one time to Florida, I think it was,</p> <p>14 to a lab where, as part of the FDA approval,</p> <p>15 it had to be inserted in a cadaver, I think,</p> <p>16 and I did a cadaver placement of a Y Mesh</p> <p>17 and we had a discussion afterwards with the</p> <p>18 various doctors involved, what we thought</p> <p>19 about it. I remember going to that one. I</p> <p>20 don't think I went to any of those other</p> <p>21 summits. I know they were scheduled. I</p> <p>22 know I was requested. I don't know if I</p> <p>23 ever went.</p> <p>24 Q Do you know if you provided other consulting</p>	<p style="text-align: right;">Page 77</p> <p>1 and it's checked "Yes" there --</p> <p>2 A Show me again the page.</p> <p>3 Q The page before, '5038.</p> <p>4 A What was the question again?</p> <p>5 Q So, in paragraph 4 of this same contract, it</p> <p>6 states that, under Preceptorship Surgical</p> <p>7 Training, the "Yes" box is checked.</p> <p>8 Do you see that?</p> <p>9 A Yes.</p> <p>10 Q It states, "Consultant shall allow visiting</p> <p>11 surgeons and visiting company sales</p> <p>12 representatives to observe surgical</p> <p>13 procedures involving the practice of</p> <p>14 continence health and pelvic floor repair</p> <p>15 procedures."</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q And that's something that actually occurred,</p> <p>19 is that Ethicon would send other doctors or</p> <p>20 sales reps to observe procedures that you</p> <p>21 were doing; is that correct?</p> <p>22 MS. VAN STEENBURGH: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: Yes.</p>

<p style="text-align: right;">Page 78</p> <p>1 BY MR. FAES:</p> <p>2 Q And you were compensated under this contract</p> <p>3 for those activities; correct?</p> <p>4 A Yes.</p> <p>5 Q If I can have you turn in this document to</p> <p>6 the page ending '5041.</p> <p>7 A (Complying.)</p> <p>8 Q And this appears to be another contract, the</p> <p>9 next one between you and Ethicon and Johnson</p> <p>10 & Johnson, dated June 5th of 2009. Do you</p> <p>11 see that at the top?</p> <p>12 A Yes.</p> <p>13 Q And if you turn in the same contract to the</p> <p>14 page ending in '5048 --</p> <p>15 A Yes.</p> <p>16 Q And it states there that "Parties agree that</p> <p>17 the compensation paid to the consultant</p> <p>18 shall not exceed \$12,000 per year, except as</p> <p>19 mutually agreed upon by the parties";</p> <p>20 correct?</p> <p>21 A That is correct.</p> <p>22 Q This appears that this is another contract</p> <p>23 that you had with Ethicon and Johnson &</p> <p>24 Johnson on June 5th of 2009 that was worth a</p>	<p style="text-align: right;">Page 80</p> <p>1 and Ethicon and Johnson & Johnson is \$16,800</p> <p>2 a year as well; correct?</p> <p>3 A Correct.</p> <p>4 Q And if you can turn to page '5070 of this</p> <p>5 document, and this is a contract between you</p> <p>6 and Ethicon and Johnson & Johnson dated</p> <p>7 February 5th of 2012; is that correct?</p> <p>8 A Correct.</p> <p>9 Q And if you turn on this one to page ending</p> <p>10 in '5078, and if you look down at the</p> <p>11 bottom, there's a maximum amount of \$28,000</p> <p>12 per year?</p> <p>13 A Right.</p> <p>14 Q So, it appears that as of March of 2012, you</p> <p>15 had another contract with Ethicon and</p> <p>16 Johnson & Johnson that was worth a maximum</p> <p>17 of \$28,000 a year; correct?</p> <p>18 A Correct.</p> <p>19 Q So, would you agree that you were under</p> <p>20 contract with Ethicon and Johnson & Johnson</p> <p>21 as a consultant pretty much continuously</p> <p>22 between April of 2006 through 2012?</p> <p>23 MS. VAN STEENBURGH: I'm going</p> <p>24 to object to the characterization for all</p>
<p style="text-align: right;">Page 79</p> <p>1 maximum of \$12,000 per year; correct?</p> <p>2 A That is correct.</p> <p>3 Q And then the next contract is on page</p> <p>4 ending '5051.</p> <p>5 A Yes.</p> <p>6 Q And it's dated January 25th of 2010.</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q And if you turn to the page ending in '5056</p> <p>10 of this contract, it appears that the</p> <p>11 maximum value of this contract between you</p> <p>12 and Ethicon and Johnson & Johnson from</p> <p>13 January 2010 is \$6,800; right?</p> <p>14 A That is correct.</p> <p>15 Q And if you turn to page '5059 of this</p> <p>16 document, and this is a consulting contract</p> <p>17 between you and Ethicon and Johnson &</p> <p>18 Johnson dated February 1st of 2011.</p> <p>19 Do you see that?</p> <p>20 A That's correct.</p> <p>21 Q And on this one, if you turn to the Exhibit</p> <p>22 A of this contract, on the page</p> <p>23 ending '5066, it appears that the maximum</p> <p>24 value of this contract from 2011 between you</p>	<p style="text-align: right;">Page 81</p> <p>1 these questions that he was a consultant for</p> <p>2 Johnson & Johnson. As I look at these, it's</p> <p>3 all with Ethicon, Inc. I'm not aware that</p> <p>4 Johnson & Johnson was signatory to any of</p> <p>5 these contracts.</p> <p>6 So, as it pertains to Ethicon, you</p> <p>7 can answer the question. But I don't see</p> <p>8 anything from --</p> <p>9 MR. FAES: You don't see</p> <p>10 "Johnson & Johnson" at the top of every page?</p> <p>11 MS. VAN STEENBURGH: I see the</p> <p>12 page, but I see the signature lines say</p> <p>13 "Ethicon Inc." And I also see the contract</p> <p>14 says "Dear Dr. Mjanger, Ethicon (the company)</p> <p>15 is pleased to have you consult." So --</p> <p>16 MR. FAES: All right. Let's</p> <p>17 not argue about it.</p> <p>18 MS. VAN STEENBURGH: That's</p> <p>19 fine. I just want to make sure I get my</p> <p>20 objection in there.</p> <p>21 BY MR. FAES:</p> <p>22 Q Would you agree that you were under contract</p> <p>23 as a consultant to Ethicon pretty much</p> <p>24 continuously between April of 2006 through</p>

<p style="text-align: right;">Page 82</p> <p>1 2012?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: Right.</p> <p>5 BY MR. FAES:</p> <p>6 Q And did you understand that you were a</p> <p>7 consultant both to Ethicon and also Johnson</p> <p>8 & Johnson, the parent company?</p> <p>9 A That, I don't know.</p> <p>10 Q Well, you can see at the top of the first</p> <p>11 contract that you signed, if you look at the</p> <p>12 first page of Exhibit No. 6, see it says</p> <p>13 Johnson & Johnson at the top; right?</p> <p>14 MS. VAN STEENBURGH: It says "a</p> <p>15 Johnson & Johnson company."</p> <p>16 THE WITNESS: Right.</p> <p>17 BY MR. FAES:</p> <p>18 Q And you understood that Ethicon was a</p> <p>19 Johnson & Johnson company; correct?</p> <p>20 A Yes.</p> <p>21 Q Was this the last consulting agreement that</p> <p>22 you signed with Ethicon and Johnson &</p> <p>23 Johnson, the one dated March 5th of 2012?</p> <p>24 A I don't know.</p>	<p style="text-align: right;">Page 84</p> <p>1 BY MR. FAES:</p> <p>2 Q We can agree that if we add up the maximum</p> <p>3 amount of all these contracts that you had</p> <p>4 with Ethicon and Johnson & Johnson over the</p> <p>5 years from 2006 to 2012, the maximum value</p> <p>6 combined of all these contracts is in excess</p> <p>7 of \$120,000; correct?</p> <p>8 MS. VAN STEENBURGH: Objection</p> <p>9 to form.</p> <p>10 THE WITNESS: I see that. In</p> <p>11 reality, what they paid me is a fraction of</p> <p>12 that.</p> <p>13 BY MR. FAES:</p> <p>14 Q Well, how much have they paid you between</p> <p>15 2006 through today?</p> <p>16 A I can't say, but --</p> <p>17 MS. VAN STEENBURGH: I think we</p> <p>18 produced that information.</p> <p>19 THE WITNESS: I can't say that.</p> <p>20 They would bring a doctor here and there in</p> <p>21 to watch me, and that is common with any kind</p> <p>22 of products we used. Visitors are interested</p> <p>23 in maybe using it or learning it and they're</p> <p>24 watching it; there's usually compensation for</p>
<p style="text-align: right;">Page 83</p> <p>1 Q But we can agree that in total, between 2006</p> <p>2 and 2012, you've had contracts with Ethicon</p> <p>3 and Johnson & Johnson worth up to \$120,000;</p> <p>4 right?</p> <p>5 MS. VAN STEENBURGH: Object to</p> <p>6 form.</p> <p>7 THE WITNESS: I was a</p> <p>8 practicing doctor using their products and</p> <p>9 the sales rep asked if I would allow new</p> <p>10 users to come in and watch me use it. So,</p> <p>11 Scott Prefer was mentioned in here, would</p> <p>12 bring doctors in to look over my shoulder.</p> <p>13 That was the consulting. And each year, they</p> <p>14 laid a paper in front of me that I had to</p> <p>15 sign. I got a little bit of money for it.</p> <p>16 It was very small amounts. It wasn't even</p> <p>17 close to what you're mentioning.</p> <p>18 They had an upper limit on those</p> <p>19 contracts. But I did my own work. They</p> <p>20 just watched me and I would answer a few</p> <p>21 questions before and after. Before having</p> <p>22 them in the OR, they did compensate me some.</p> <p>23 It could be maybe two doctors one month and</p> <p>24 half a year no doctors.</p>	<p style="text-align: right;">Page 85</p> <p>1 letting someone in the OR.</p> <p>2 BY MR. FAES:</p> <p>3 Q So, I think I already asked this, but to the</p> <p>4 best of your knowledge, the last consulting</p> <p>5 contract, other than in litigation, that</p> <p>6 you've signed with Ethicon or Johnson &</p> <p>7 Johnson was in March of 2012; right?</p> <p>8 A I can't recall. I see there's one, yeah. I</p> <p>9 haven't done any work for them. Of course,</p> <p>10 there's not been that many doctors. They</p> <p>11 learn it in residency. But there was a time</p> <p>12 when doctors had to learn and they would</p> <p>13 come and watch.</p> <p>14 Q When did you stop doing consulting work for</p> <p>15 Ethicon and Johnson & Johnson?</p> <p>16 A I can't recall.</p> <p>17 Q Why did you stop doing consulting work for</p> <p>18 Ethicon and Johnson & Johnson?</p> <p>19 A I'm sure there was no need for it anymore.</p> <p>20 Q Why was there no -- what was your</p> <p>21 understanding of why there was no need for</p> <p>22 your consulting work anymore?</p> <p>23 A The new doctors doing this work, they are</p> <p>24 trained from residency to put in slings.</p>

Page 86	Page 88
<p>1 There was a time when the sling was</p> <p>2 relatively new and there were practicing</p> <p>3 doctors who were brought in by the</p> <p>4 salespeople to watch and observe. That's</p> <p>5 what I did. It was not much money and it</p> <p>6 was not much time. It was just letting them</p> <p>7 stand and watch while I operate and ask</p> <p>8 questions.</p> <p>9 Q So, when was the last time that you trained</p> <p>10 someone on either the TVT or TVT-O?</p> <p>11 A I can't totally recall. I think it's been</p> <p>12 several years since I've had an observer in</p> <p>13 the OR for that purpose.</p> <p>14 Q And I should have asked this in my question.</p> <p>15 But is the answer the same with regard to</p> <p>16 the TVT-Exact as well?</p> <p>17 A Yeah. Whatever TVT I did, they would come</p> <p>18 in and observe sometimes. But it's been a</p> <p>19 long time. I can't recall.</p> <p>20 Q And have you -- you've never been a trainer</p> <p>21 or preceptor on the TVT Abbrevio; correct?</p> <p>22 A Way back -- no, no, I can't recall. I can't</p> <p>23 recall that. It's been so many years. I</p> <p>24 know I've had people in the operating room</p>	<p>1 A I don't even know.</p> <p>2 Q Do you remember when the last time it was</p> <p>3 that you saw a sales rep for Ethicon and</p> <p>4 Johnson & Johnson?</p> <p>5 A There is a lady -- it's hard to remember.</p> <p>6 Emily Egan I think works for them.</p> <p>7 Q But you don't recall the last time you've</p> <p>8 ever seen a sales rep for Ethicon and</p> <p>9 Johnson & Johnson?</p> <p>10 A No. I see Emily Egan. She does other</p> <p>11 products for them, too. There's been no</p> <p>12 interest around slings for a long time.</p> <p>13 Q What other products does she have that you</p> <p>14 use?</p> <p>15 A Sutures.</p> <p>16 Q And if you look in the body of this e-mail,</p> <p>17 it states that "Dr. Mjanger asked me to</p> <p>18 inquire about getting the TVT-O sling</p> <p>19 stocked in our laser-cut mesh. The sling is</p> <p>20 exactly the same as the TVT-O that you now</p> <p>21 order, only the mesh is laser cut versus</p> <p>22 mechanically cut."</p> <p>23 A Yes.</p> <p>24 Q "The product code is 810081L (regular</p>
Page 87	Page 89
<p>1 watching. I can't recall all the details on</p> <p>2 the training. I can't recall.</p> <p>3 Q Okay.</p> <p>4 (Exhibit No. 7 Marked.)</p> <p>5</p> <p>6 BY MR. FAES:</p> <p>7 Q Doctor, I'm going to hand you what's been</p> <p>8 marked as Exhibit No. 7 to your deposition.</p> <p>9 A Okay.</p> <p>10 Q And this is a document dated August 17th of</p> <p>11 2009.</p> <p>12 Do you see that at the top?</p> <p>13 A Yes, I see that.</p> <p>14 Q And this is from a Laura Mettner.</p> <p>15 Do you see that at the top?</p> <p>16 A Yes.</p> <p>17 Q Do you know who Laura Mettner is?</p> <p>18 A Yeah. She's the sales rep for Ethicon.</p> <p>19 Q Do you know, is she still a sales rep for</p> <p>20 Ethicon and Johnson & Johnson?</p> <p>21 A I haven't seen her for a long time, so I</p> <p>22 don't know.</p> <p>23 Q Who is your current sales rep for Ethicon</p> <p>24 and Johnson & Johnson?</p>	<p>1 product code is 810081) and the price is</p> <p>2 exactly the same as the regular TVT-O</p> <p>3 sling."</p> <p>4 Do you see that?</p> <p>5 A Yes.</p> <p>6 Q Do you recall, in 2009, asking the sales rep</p> <p>7 for Ethicon and Johnson & Johnson if you</p> <p>8 could get the laser-cut TVT-O sling stocked</p> <p>9 in the hospital?</p> <p>10 A I can't recall that.</p> <p>11 Q Do you have any reason to dispute this</p> <p>12 fact --</p> <p>13 A No.</p> <p>14 Q -- that -- reflected by Ms. Mettner that you</p> <p>15 had asked your sales rep to inquire about</p> <p>16 getting the TVT-O laser cut stocked in the</p> <p>17 hospital?</p> <p>18 A No.</p> <p>19 MS. VAN STEENBURGH: Let him</p> <p>20 finish the question before you answer. You</p> <p>21 know where he's going.</p> <p>22 THE WITNESS: Okay. But no.</p> <p>23 BY MR. FAES:</p> <p>24 Q This is to Rjgary@healtheast.org.</p>

<p style="text-align: right;">Page 90</p> <p>1 Do you know who that is?</p> <p>2 A No. I know HealthEast.</p> <p>3 Q So, HealthEast would have been one of the</p> <p>4 hospitals where you had privileges to</p> <p>5 practice in in 2009; is that right?</p> <p>6 A Right. Yeah.</p> <p>7 (Exhibit No. 8 Marked.)</p> <p>8</p> <p>9 BY MR. FAES:</p> <p>10 Q Doctor, I'm going to hand you what's been</p> <p>11 marked as Exhibit No. 8 to your deposition.</p> <p>12 And this is an e-mail dated May 25th of</p> <p>13 2010.</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q And these e-mails kind of go in reverse</p> <p>17 order, so I'm going to actually start with</p> <p>18 the first communication on the string which</p> <p>19 actually starts at the bottom of the first</p> <p>20 page, at 8-25 under Tricia and Katy.</p> <p>21 Do you see that?</p> <p>22 A Yes.</p> <p>23 Q It's an e-mail from Laura Mettner, who was</p> <p>24 your Ethicon sales rep in 2010; is that</p>	<p style="text-align: right;">Page 92</p> <p>1 TVT-Exact, that it was only available in the</p> <p>2 laser-cut mesh?</p> <p>3 A I cannot remember that.</p> <p>4 Q And then it goes on to state, "I have talked</p> <p>5 to Dr. Ashford about it as well. I do see</p> <p>6 all the surgeons who use TVT to switch to</p> <p>7 TVT-Exact."</p> <p>8 Do you see that?</p> <p>9 A Yes.</p> <p>10 Q Who's Dr. Ashford?</p> <p>11 A It's a gynecologist in St. Paul. Or</p> <p>12 Maplewood.</p> <p>13 Q He's not someone that you work with; right?</p> <p>14 A No.</p> <p>15 Q Okay. Did you have an understanding, in</p> <p>16 2010, that sales reps from Ethicon and</p> <p>17 Johnson & Johnson believed that all surgeons</p> <p>18 who were using the TVT device would switch</p> <p>19 to the TVT-Exact?</p> <p>20 MS. VAN STEENBURGH: Object to</p> <p>21 form.</p> <p>22 THE WITNESS: No. I cannot</p> <p>23 recall any of it.</p> <p>24</p>
<p style="text-align: right;">Page 91</p> <p>1 right?</p> <p>2 A I see it, yeah.</p> <p>3 Q And it states, "We are also launching a new</p> <p>4 retropubic sling (TVT-Exact) in June 2010.</p> <p>5 This sling could replace your current TVT</p> <p>6 retropubic (810041B or 810041BL in the laser</p> <p>7 cut form). TVT-Exact already comes in laser</p> <p>8 cut. I have shown Dr. Mjanger and he would</p> <p>9 like to try this sling when it becomes</p> <p>10 available and foresees using this</p> <p>11 exclusively for his retropubic slings."</p> <p>12 Do you see that?</p> <p>13 A Yes.</p> <p>14 Q Is this accurate, that in or around May of</p> <p>15 2010, that your sales rep showed you the</p> <p>16 TVT-Exact and you foresaw using it</p> <p>17 exclusively for your retropubic slings?</p> <p>18 A I cannot remember that, but it makes sense.</p> <p>19 Q Did you have an understanding at that time</p> <p>20 that the TVT-Exact only came in laser cut</p> <p>21 and was not available in mechanical cut?</p> <p>22 A I cannot remember that.</p> <p>23 Q Do you remember if you believed that that</p> <p>24 was a potential clinical benefit from the</p>	<p style="text-align: right;">Page 93</p> <p>1 BY MR. FAES:</p> <p>2 Q If you turn to the following page in the</p> <p>3 same communication string, just flip it</p> <p>4 over, it states that "The advantages of the</p> <p>5 TVT-Exact are that a disposable handle is</p> <p>6 now included in the packaging (no need for</p> <p>7 the reusable introducer - this will save</p> <p>8 processing time). The needle is smaller</p> <p>9 (three millimeters). The existing TVT sling</p> <p>10 is 5 millimeters."</p> <p>11 Do you see that?</p> <p>12 A Yes, I see that.</p> <p>13 Q Is that your understanding of the</p> <p>14 differences between the TVT-Exact and the</p> <p>15 TVT retropubic?</p> <p>16 A Yes.</p> <p>17 Q Is the fact that the TVT-Exact needling is</p> <p>18 smaller than the TVT retropubic a potential</p> <p>19 benefit to patients?</p> <p>20 MS. VAN STEENBURGH: Object to</p> <p>21 form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MR. FAES:</p> <p>24 Q Do you feel like using a 3 millimeter needle</p>

<p style="text-align: right;">Page 94</p> <p>1 in the TVT-Exact is a potentially safer</p> <p>2 alternative to using the 5 millimeter needle</p> <p>3 in the TVT retropubic?</p> <p>4 A No.</p> <p>5 Q You don't feel like a smaller needle leaves</p> <p>6 less -- strike that.</p> <p>7 You don't feel like a smaller needle,</p> <p>8 as used in the TVT-Exact, makes it less</p> <p>9 likely that you'll do damage to surrounding</p> <p>10 tissues and organs when you're doing the TVT</p> <p>11 procedure?</p> <p>12 A No.</p> <p>13 Q Isn't that one of the reasons, though, why</p> <p>14 you use the TVT-Exact exclusively now as</p> <p>15 opposed to the TVT retropubic?</p> <p>16 A Not for safety but for ease of insertion.</p> <p>17 It's a smaller -- it's a lot easier to</p> <p>18 insert it. It's a smaller hole, two</p> <p>19 millimeters smaller.</p> <p>20 Q Would you agree that if a medical device is</p> <p>21 easier to insert for a physician, that is a</p> <p>22 potential safety benefit to the patient?</p> <p>23 A Yes/no. If you put it in the wrong place,</p> <p>24 it matters. But if you put it in the right</p>	<p style="text-align: right;">Page 96</p> <p>1 think it feels better when I put it in. If</p> <p>2 it goes in the right track, two millimeters</p> <p>3 doesn't really make a difference in safety,</p> <p>4 if it's put where it should be. It's hard to</p> <p>5 answer your question.</p> <p>6 BY MR. FAES:</p> <p>7 Q Okay. If you go on and read the same</p> <p>8 document, it states, "The TVT-Exact" -- well</p> <p>9 strike that. Let me back up.</p> <p>10 When the sales rep described the</p> <p>11 TVT-Exact to you, is one of the things that</p> <p>12 they showed and explained to you that the</p> <p>13 TVT-Exact needle is smaller than the TVT</p> <p>14 retropubic needle?</p> <p>15 MS. VAN STEENBURGH: Object to</p> <p>16 form.</p> <p>17 THE WITNESS: What was the</p> <p>18 question?</p> <p>19 BY MR. FAES:</p> <p>20 Q When you were first shown the TVT-Exact</p> <p>21 product by representatives from Ethicon and</p> <p>22 Johnson & Johnson, is one of the things they</p> <p>23 explained to you was that the TVT-Exact</p> <p>24 needle was smaller than the TVT retropubic</p>
<p style="text-align: right;">Page 95</p> <p>1 place, it shouldn't really matter. It's</p> <p>2 easier for me to insert it. I have a better</p> <p>3 feel with a thinner one. If it's done</p> <p>4 right, it shouldn't really be any different</p> <p>5 risk.</p> <p>6 Q But you'd agree that if one device is easier</p> <p>7 to insert than another, over time, the</p> <p>8 safety and efficacy rates for that device</p> <p>9 that's easier to insert will be higher than</p> <p>10 the one that's more difficult to insert;</p> <p>11 correct?</p> <p>12 MS. VAN STEENBURGH: Object to</p> <p>13 form.</p> <p>14 THE WITNESS: It's not more</p> <p>15 difficult. It just takes a little more force</p> <p>16 to put it in. It's not more difficult.</p> <p>17 BY MR. FAES:</p> <p>18 Q So, are you saying -- so, are you now saying</p> <p>19 that the TVT-Exact is not easier to place</p> <p>20 than the TVT retropubic --</p> <p>21 MS. VAN STEENBURGH: Object to</p> <p>22 form.</p> <p>23 THE WITNESS: No. It feels</p> <p>24 better in my hand. It's a better tool. I</p>	<p style="text-align: right;">Page 97</p> <p>1 needle?</p> <p>2 A I saw that when I got it in my hand.</p> <p>3 Q Okay. And did they explain to you that that</p> <p>4 was an advantage, as the sales rep says in</p> <p>5 this e-mail here?</p> <p>6 A I can't recall what he said to me.</p> <p>7 Q It also goes on to state in the same e-mail</p> <p>8 that the TVT-Exact only requires one cysto</p> <p>9 during the procedure. Traditional TVT</p> <p>10 required two cystos, because you could not</p> <p>11 place both needles and then place the cysto</p> <p>12 in the urethra (the needles were too large</p> <p>13 to allow that)."</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q Do you have an understanding that that's one</p> <p>17 of the differences between the TVT-Exact and</p> <p>18 the traditional TVT?</p> <p>19 A Yes.</p> <p>20 Q Did you have an understanding that that's a</p> <p>21 potential advantage to both the doctor and</p> <p>22 the patient with the TVT-Exact over the TVT?</p> <p>23 MS. VAN STEENBURGH: Object to</p> <p>24 form.</p>

<p style="text-align: right;">Page 98</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. FAES:</p> <p>3 Q And the line below it states, "Dr. Mjanger</p> <p>4 is the biggest proponent of this (and I</p> <p>5 believe he is the largest user of the TVT</p> <p>6 retropubic)."</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q Do you agree with this statement, that you</p> <p>10 were a big proponent of the TVT-Exact at</p> <p>11 this time, in 2010?</p> <p>12 MS. VAN STEENBURGH: Object to</p> <p>13 form.</p> <p>14 THE WITNESS: I can't recall</p> <p>15 that. What I recall was when the TVT-Exact</p> <p>16 was stuck in my hand, it felt good. It's</p> <p>17 like getting two different screw drivers.</p> <p>18 One feels good in your hand but they do the</p> <p>19 exact same thing. I can do the exact same</p> <p>20 procedure. One felt a little bit better in</p> <p>21 the hand. There's less cysto, a little</p> <p>22 quicker. You save a step. The advantages of</p> <p>23 the newer model is better than the old model,</p> <p>24 I think.</p>	<p style="text-align: right;">Page 100</p> <p>1 marked as Exhibit No. 9 to your deposition.</p> <p>2 And this is an e-mail from Laura</p> <p>3 Mettner, which is your sales rep from</p> <p>4 Ethicon and Johnson & Johnson, to you; is</p> <p>5 that right?</p> <p>6 A Yes.</p> <p>7 Q And this is dated June 28th of 2010?</p> <p>8 A Yes.</p> <p>9 Q Do you recall getting this e-mail?</p> <p>10 A No.</p> <p>11 Q You don't have any reason to dispute that</p> <p>12 this is an e-mail that would have been</p> <p>13 received and reviewed by you, do you? Take</p> <p>14 your time to review it, if you need to, in</p> <p>15 its entirety.</p> <p>16 A (Witness reviews the document.)</p> <p>17 Q Let me know when you're ready.</p> <p>18 A Okay. Let me read it.</p> <p>19 (Witness reviews the document.)</p> <p>20 I see this. I can't recall it, but I</p> <p>21 see it.</p> <p>22 Q But as you sit here today, you don't have</p> <p>23 any reason to dispute that you would have</p> <p>24 received this e-mail in 2010, do you?</p>
<p style="text-align: right;">Page 99</p> <p>1 BY MR. FAES:</p> <p>2 Q Okay. You would agree that at least in your</p> <p>3 hands, the TVT-Exact feels better than the</p> <p>4 classic TVT retropubic?</p> <p>5 MS. VAN STEENBURGH: Object to</p> <p>6 form.</p> <p>7 THE WITNESS: Correct.</p> <p>8 BY MR. FAES:</p> <p>9 Q If you see in the paragraph above, it</p> <p>10 states, "Lastly, the design of the handle</p> <p>11 offers more tactile feel to the surgeon when</p> <p>12 they place the sling. A rigid catheter</p> <p>13 guide is still required."</p> <p>14 Do you see that?</p> <p>15 A Yeah.</p> <p>16 Q Is that an accurate description of what you</p> <p>17 were telling me about earlier, that the</p> <p>18 TVT-Exact handle offers a more tactile feel</p> <p>19 to the surgeon when you place the Exact?</p> <p>20 A Yes.</p> <p>21 (Exhibit No. 9 Marked.)</p> <p>22</p> <p>23 BY MR. FAES:</p> <p>24 Q Doctor, I'm going to hand you what's been</p>	<p style="text-align: right;">Page 101</p> <p>1 A No.</p> <p>2 Q And you see it states, "Dear Dr. Mjanger,</p> <p>3 Just wanted to update you on the status of</p> <p>4 getting the TVT-Exact and the laser-cut mesh</p> <p>5 for the TVT-O into United and Same Day."</p> <p>6 Do you see that?</p> <p>7 A Yes.</p> <p>8 Q And United and Same Day are hospitals where</p> <p>9 you were performing surgeries and had</p> <p>10 privileges at this time, in 2010; correct?</p> <p>11 A Right.</p> <p>12 Q And "All the information and requests have</p> <p>13 been made for both and we are simply waiting</p> <p>14 for the value analysis committee to meet and</p> <p>15 approve them."</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q Do you recall at this time, in 2010, that</p> <p>19 you were wanting to get both the TVT-Exact</p> <p>20 with the laser-cut mesh and the TVT-O with</p> <p>21 the laser-cut mesh into the hospitals where</p> <p>22 you were practicing so you could use them?</p> <p>23 A I don't remember that.</p> <p>24 Q If you see in the paragraph below, it asks,</p>

<p style="text-align: right;">Page 102</p> <p>1 "What can we do in the meantime to bypass 2 the value analysis committee by talking to 3 either Dr. Foley or Joan Kidd at United?" 4 Do you see that? 5 A Yes. 6 Q Do you recall being asked for assistance by 7 the sales rep from Ethicon and Johnson & 8 Johnson in expediting the entry of the 9 TVT-Exact and the TVT-O laser cut into the 10 hospitals where you practiced? 11 A No. 12 Q Do you remember doing anything to help get 13 those -- 14 A No. 15 Q -- products into the hospitals? 16 A I don't remember. 17 (Exhibit No. 10 Marked.) 18 19 BY MR. FAES: 20 Q Doctor, I'm going to hand you what's been 21 marked as Exhibit No. 10 to your deposition. 22 And this is a document titled "Valuation 23 Form." And you see the product is for a 24 TVT-O laser cut.</p>	<p style="text-align: right;">Page 104</p> <p>1 "Clinical Benefit to new product." And it 2 states "Yes." 3 Do you see that? 4 A I see that. But this is not signed by me, 5 so I don't know if I ever saw this form. 6 Q Do you recall whether or not you actually 7 signed this form? 8 A I can't recall, no. 9 Q Let me get through the rest of it and I'll 10 ask you some questions about that. 11 And it states, "TVT-O laser-cut mesh 12 is also laser cut which allows the mesh to 13 lie flatter beneath the urethra and prevents 14 banding of the mesh (better for patient). 15 There is no difference in price between the 16 laser cut and mechanical cut." 17 Do you see that? 18 A Yes. 19 Q And it's got a spot for your signature, but 20 at least this version of the document is not 21 signed; right? 22 A Correct. 23 Q Do you recall ever seeing this document 24 before?</p>
<p style="text-align: right;">Page 103</p> <p>1 Do you see that? 2 A Yes. 3 Q And you see down at the bottom, it states, 4 under Requesting Physician, "Dr. Mjanger." 5 That's you; right? 6 A Yes. 7 Q And it states that "Evaluation occur within 8 United and Same Day Surgery." And it 9 states, "Yes, 2 TVT-O laser-cut mesh were 10 brought in and one has been used to date." 11 Do you recall the sales rep bringing 12 in a laser-cut mesh for you to use before 13 the hospital actually was ordering it and 14 making it available? 15 A No, I can't remember that. 16 Q Do you remember that from time to time, a 17 sales rep would bring you in a TVT or TVT-O 18 or other mesh device for you to use or try 19 for the first time? 20 A I can't remember. 21 Q So, you don't think that's ever happened in 22 the course of your 20-plus year career? 23 A I can't remember. 24 Q And it states, on this Evaluation Form,</p>	<p style="text-align: right;">Page 105</p> <p>1 A No. 2 Q Do you recall if you signed this document? 3 A No. 4 Q Would you sign this document today if you 5 were asked to sign it? 6 A I can't answer that. This looks to me like 7 it's something that's written by the sales 8 rep. I have not signed it. I can't recall 9 ever seeing this thing. 10 Q You don't answer whether or not -- well, 11 strike that. 12 You can't answer whether you'd sign 13 this document today? 14 A No, I can't answer that. 15 Q So, if -- for example, now you use the TVT-O 16 laser-cut mesh; right? 17 A Right. 18 Q If, for some reason, the hospital switched 19 back to TVT-O mechanically cut mesh, would 20 you want the laser-cut mesh in the TVT-O to 21 still be available, or would you not care? 22 A I don't know. I would have to -- I would 23 have to look into it. I just can't answer 24 that right now.</p>

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<p>1 Q Do you remember from the documents that</p> <p>2 we've looked at in the last five, ten</p> <p>3 minutes or so whether or not you were</p> <p>4 actually trying to get the TVT-O laser-cut</p> <p>5 mesh into your hospitals in 2010?</p> <p>6 A I saw a document, but I can't remember</p> <p>7 anything from 2010 that we did. I just</p> <p>8 cannot.</p> <p>9 Q So, let me ask you about this document. It</p> <p>10 states that the TVT-O laser-cut mesh</p> <p>11 clinical benefit to the new product, yes.</p> <p>12 Do you agree with that statement or</p> <p>13 disagree with that statement, that there's a</p> <p>14 clinical benefit to the TVT-O laser cut over</p> <p>15 the TVT-O mechanical cut?</p> <p>16 A All I can remember is that years ago,</p> <p>17 probably back this time here, there was some</p> <p>18 talk about laser cut or no laser cut. I</p> <p>19 haven't heard more talk about it ever since,</p> <p>20 before you brought it up here. I'm curious</p> <p>21 if they had one or the other. I can't -- I</p> <p>22 can't answer that.</p> <p>23 Q So, you can't answer the question, as you</p> <p>24 sit here today, whether or not you agree or</p>	<p>1 allows the mesh to lie flatter beneath the</p> <p>2 urethra and prevents banding of the mesh?</p> <p>3 A I spoke about it earlier today, that if you</p> <p>4 don't tug on it, it makes no difference. If</p> <p>5 you tug on it, it makes a difference. You</p> <p>6 shouldn't tug on it. If you inadvertently</p> <p>7 tug on it, I think the laser mesh is a</p> <p>8 little stiffer and lays better.</p> <p>9 Q But irregardless of who wrote this or</p> <p>10 whether you tug on the mesh or any of those</p> <p>11 other factors, do you have an opinion, as</p> <p>12 you sit here today, as to whether or not</p> <p>13 laser-cut mesh allows the mesh to lie</p> <p>14 flatter under the urethra and prevents</p> <p>15 banding of the mesh?</p> <p>16 MS. VAN STEENBURGH: Objection,</p> <p>17 asked and answered. You can answer that</p> <p>18 question.</p> <p>19 THE WITNESS: When you lay it</p> <p>20 in, if you just lay it there without tension</p> <p>21 on it, it makes no difference. If you tug on</p> <p>22 it, it makes a difference.</p> <p>23 BY MR. FAES:</p> <p>24 Q So, is it your testimony that if it's</p>
Page 107	Page 109
<p>1 disagree with the statement that the TVT-O</p> <p>2 laser-cut mesh provides a clinical benefit</p> <p>3 over the TVT mechanical?</p> <p>4 A No, I can't.</p> <p>5 Q It also states, "Laser-cut mesh is also" --</p> <p>6 strike that.</p> <p>7 It also states that "The laser-cut</p> <p>8 mesh allows the mesh to lie flatter beneath</p> <p>9 the urethra and prevents banding of the</p> <p>10 mesh."</p> <p>11 Do you see that?</p> <p>12 A Yes, I see that, sir.</p> <p>13 Q Do you agree or disagree with that</p> <p>14 statement?</p> <p>15 A I can't answer it like that. This seems</p> <p>16 like it's a form letter written by the sales</p> <p>17 rep. That's her or his words here. It's</p> <p>18 not mine. I didn't write this. The</p> <p>19 discussion about laying flat or not laying</p> <p>20 flat is a whole different discussion. I</p> <p>21 can't give any answer to this form here</p> <p>22 really.</p> <p>23 Q So, as you sit here today, you have no</p> <p>24 opinion as to whether the laser-cut mesh</p>	<p>1 laser-cut mesh and you tug on it, the</p> <p>2 laser-cut mesh allows the mesh to lie</p> <p>3 flatter beneath the urethra and prevents</p> <p>4 banding of the mesh?</p> <p>5 A Yes. It frays less. It takes a little bit</p> <p>6 more to distort it. It's like a rubber</p> <p>7 band. You pull it and it won't go back. It</p> <p>8 takes a little more pulling before it won't</p> <p>9 go back.</p> <p>10 Q So, you'd agree that the laser-cut mesh is</p> <p>11 more resistant to deformation than the</p> <p>12 mechanically cut mesh if you pull on it,</p> <p>13 which allows it to lie flatter beneath the</p> <p>14 urethra and prevents banding of the mesh;</p> <p>15 correct?</p> <p>16 A That, I'd agree with.</p> <p>17 Q And that's better for the patient; correct?</p> <p>18 A It can be.</p> <p>19 Q And you don't recall one way or the other if</p> <p>20 you signed this document in 2010 or at any</p> <p>21 time?</p> <p>22 A No.</p> <p>23 Q If it turns out that you did sign this in</p> <p>24 2010, would you stand by the statements that</p>

<p style="text-align: right;">Page 110</p> <p>1 you made in this document that you signed?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: I didn't make the</p> <p>5 statement. I -- this is written by someone</p> <p>6 else and my signature is not on it. I cannot</p> <p>7 answer in that form. I can't speculate that.</p> <p>8 BY MR. FAES:</p> <p>9 Q So, if someone brought this to you to sign</p> <p>10 today, let's say your current rep for</p> <p>11 Ethicon and Johnson & Johnson brought this</p> <p>12 to you to sign because they wanted to make</p> <p>13 sure that the TVT-O laser-cut mesh stayed in</p> <p>14 the hospitals where you're practicing now,</p> <p>15 would you feel comfortable signing this</p> <p>16 document today or not?</p> <p>17 MS. VAN STEENBURGH: Object to</p> <p>18 form.</p> <p>19 THE WITNESS: I don't see any</p> <p>20 reason why I should feel comfortable signing</p> <p>21 it. She's put a whole sales pitch into this.</p> <p>22 There's someone she's talking to. Who does</p> <p>23 this form go to?</p> <p>24</p>	<p style="text-align: right;">Page 112</p> <p>1 THE WITNESS: Well, if my goal</p> <p>2 was to get it in -- I don't know. The way</p> <p>3 it's written, it's more like a sales pitch</p> <p>4 than anything else.</p> <p>5 BY MR. FAES:</p> <p>6 Q Okay. So, let's assume for the purposes of</p> <p>7 this question that there was a potential</p> <p>8 that the TVT-O laser-cut mesh might be -- no</p> <p>9 longer be available in the hospitals where</p> <p>10 you have privileges and practice.</p> <p>11 If an Ethicon sales rep came to you</p> <p>12 and said "Hey, I'd like you to sign this</p> <p>13 form in order to convince the hospital to</p> <p>14 continue to make the TVT-O laser-cut mesh</p> <p>15 available in your hospital," would you feel</p> <p>16 comfortable signing this form today?</p> <p>17 MS. VAN STEENBURGH: Object to</p> <p>18 form.</p> <p>19 THE WITNESS: I would ask for</p> <p>20 more information. I would have to know why</p> <p>21 isn't it available? Is there something --</p> <p>22 have you discovered something wrong with it?</p> <p>23 Is there any article on it? I would need</p> <p>24 more information. I wouldn't just sign it</p>
<p style="text-align: right;">Page 111</p> <p>1 BY MR. FAES:</p> <p>2 Q Well, I assume it goes to your hospital to</p> <p>3 convince them to put the -- let's assume for</p> <p>4 the purpose of this question that this form</p> <p>5 goes to your hospital to -- for them to</p> <p>6 evaluate whether or not to put that product</p> <p>7 in the hospital.</p> <p>8 MS. VAN STEENBURGH: Object to</p> <p>9 form.</p> <p>10 THE WITNESS: I can't speculate</p> <p>11 on the form. It doesn't say who it goes to.</p> <p>12 It doesn't say who wrote it. It's some</p> <p>13 salesperson writing it. I can't answer it.</p> <p>14 There's no address to. There's no signature</p> <p>15 on it. I don't know who made this statement.</p> <p>16 I just can't say much about that form. It's</p> <p>17 a blank form.</p> <p>18 BY MR. FAES:</p> <p>19 Q Okay. So, you stated that you can't think</p> <p>20 of any reason why you would feel comfortable</p> <p>21 signing this today.</p> <p>22 Did I hear that testimony correctly?</p> <p>23 MS. VAN STEENBURGH: Object to</p> <p>24 form.</p>	<p style="text-align: right;">Page 113</p> <p>1 blind.</p> <p>2 BY MR. FAES:</p> <p>3 Q Is there something in particular about</p> <p>4 anything in this form that makes you</p> <p>5 uncomfortable about signing it?</p> <p>6 MS. VAN STEENBURGH: Object to</p> <p>7 form.</p> <p>8 THE WITNESS: I don't know what</p> <p>9 it's for. I don't know who it's for or who</p> <p>10 it's going to.</p> <p>11 You know, at that time I didn't know</p> <p>12 anything bad about laser mesh. If they took</p> <p>13 it away today, it's a whole different</p> <p>14 situation. I would have to find out why</p> <p>15 it's taken away.</p> <p>16 BY MR. FAES:</p> <p>17 Q So, other than you don't know what this form</p> <p>18 is for and you don't know where it goes, is</p> <p>19 there anything about the content of this</p> <p>20 form that makes you uncomfortable? Do you</p> <p>21 feel like anything is factually inaccurate</p> <p>22 on this form?</p> <p>23 MS. VAN STEENBURGH: Object to</p> <p>24 form.</p>

<p style="text-align: right;">Page 114</p> <p>1 THE WITNESS: You know, this</p> <p>2 looks like -- they're talking about the price</p> <p>3 of it and all this stuff. It seems like it's</p> <p>4 not really meant for -- I don't know. I</p> <p>5 don't think I would sign it unless I would</p> <p>6 have more information. I wouldn't just sign</p> <p>7 it.</p> <p>8 BY MR. FAES:</p> <p>9 Q What more information would you need in</p> <p>10 order to sign it?</p> <p>11 A Why isn't it available? Why are they taking</p> <p>12 it away? Maybe there's more information I</p> <p>13 didn't have. I would have to figure it out.</p> <p>14 MR. FAES: Off the record.</p> <p>15 (Recess began - 11:07 a.m.)</p> <p>16 (Recess ended - 11:14 a.m.)</p> <p>17 BY MR. FAES:</p> <p>18 Q Doctor, we're back on the record after a</p> <p>19 short break. Are you ready to proceed?</p> <p>20 A I'm ready.</p> <p>21 Q Okay. Sorry. I didn't hear you.</p> <p>22 So, earlier, before we went on break,</p> <p>23 we were looking at an evaluation form for</p> <p>24 the laser-cut TVT-O product.</p>	<p style="text-align: right;">Page 116</p> <p>1 Q Do you remember if there were any clinical</p> <p>2 benefits to that product that made it better</p> <p>3 than the TVT-O sling?</p> <p>4 A I don't know what the result turned out to</p> <p>5 be, but I know it was suggested as a less</p> <p>6 mesh sling, shorter sling, that hopefully</p> <p>7 would not cause the groin pain. I think</p> <p>8 that was the motivation. How it turned out,</p> <p>9 I don't know. I haven't heard much about</p> <p>10 it, because I haven't used TVT much lately.</p> <p>11 I've kind of been away from it.</p> <p>12 Q So, did you have an understanding that the</p> <p>13 TVT Abbrevio had less mesh and would</p> <p>14 potentially cause less inner thigh pain for</p> <p>15 the patient which would be a benefit for the</p> <p>16 patient?</p> <p>17 A That was supposed to be the idea.</p> <p>18 Q But you don't currently use the TVT Abbrevio</p> <p>19 today when you use TVT obturator slings?</p> <p>20 A It's been so long, I can't remember which</p> <p>21 one I put in last time. I can't remember.</p> <p>22 MS. VAN STEENBURGH: You mean</p> <p>23 as to the Abbrevio?</p> <p>24 THE WITNESS: I can't recall</p>
<p style="text-align: right;">Page 115</p> <p>1 Do you remember that?</p> <p>2 A Right.</p> <p>3 Q And you're not sure, as you sit here today,</p> <p>4 whether you ultimately signed that form back</p> <p>5 in 2010 or at any other time; right?</p> <p>6 A Right. I'm quite sure I didn't sign it. My</p> <p>7 signature's not on it.</p> <p>8 Q But do you remember ever signing a similar</p> <p>9 form for the TVT Abbrevio product?</p> <p>10 A No.</p> <p>11 Q Did you have an understanding that the TVT</p> <p>12 Abbrevio product is also only offered in</p> <p>13 laser-cut mesh?</p> <p>14 A In laser cut?</p> <p>15 Q Yes.</p> <p>16 A No.</p> <p>17 Q So, you don't know whether the TVT Abbrevio</p> <p>18 is offered in mechanically cut mesh or not?</p> <p>19 A I don't know.</p> <p>20 Q When was the TVT Abbrevio first described to</p> <p>21 you?</p> <p>22 A I can't remember.</p> <p>23 Q You put a few of them in before; right?</p> <p>24 A Yeah.</p>	<p style="text-align: right;">Page 117</p> <p>1 which one it was.</p> <p>2 (Exhibit No. 11 Marked.)</p> <p>3</p> <p>4 BY MR. FAES:</p> <p>5 Q Doctor, I'm going to hand you what's been</p> <p>6 marked as Exhibit No. 11 to your deposition.</p> <p>7 And this is a form entitled "Surgery New</p> <p>8 Product/Procedure Request Form."</p> <p>9 Do you see that at the top?</p> <p>10 A Yes.</p> <p>11 Q And if you see about a third of the way</p> <p>12 down, under Physician/Requested By, it says</p> <p>13 "Dr. Ron Mjanger."</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q And that's you; right?</p> <p>17 A Yes.</p> <p>18 Q And this document is actually signed by you;</p> <p>19 right?</p> <p>20 A Yes.</p> <p>21 Q Is that your signature there?</p> <p>22 A Yes, it is.</p> <p>23 Q Did you sign this document?</p> <p>24 A I assume so.</p>

<p style="text-align: right;">Page 118</p> <p>1 Q Do you recall signing this document?</p> <p>2 A No, no.</p> <p>3 Q And it states, under Impact on Outcome,</p> <p>4 Clinical Benefits, it states, "Less tissue</p> <p>5 dissection, 83 percent less mesh in the</p> <p>6 adductor muscles, 32 percent less mesh</p> <p>7 overall."</p> <p>8 Do you see that?</p> <p>9 A Yes.</p> <p>10 Q Do you believe that a device like the</p> <p>11 Abbrevio that has less tissue dissection</p> <p>12 offers a clinical benefit over the TVT-O?</p> <p>13 A That was the theory.</p> <p>14 Q Do you agree that a mesh device which leaves</p> <p>15 83 percent -- strike that.</p> <p>16 Would you agree that a mesh device</p> <p>17 such as the Abbrevio which leaves 83 percent</p> <p>18 less mesh in the adductor muscles and 32</p> <p>19 percent less mesh overall offers a clinical</p> <p>20 benefit over the TVT-O device?</p> <p>21 A Like I said, that was a theory when it came</p> <p>22 out.</p> <p>23 Q Well, it states here that this is a clinical</p> <p>24 benefit that's expected to be achieved from</p>	<p style="text-align: right;">Page 120</p> <p>1 different product, does that not make it a</p> <p>2 safer alternative product?</p> <p>3 A Theoretically, yes.</p> <p>4 Q It also states that it's a hundred percent</p> <p>5 adjustable.</p> <p>6 Do you see that?</p> <p>7 A Yes.</p> <p>8 Q What's your understanding of what that</p> <p>9 means, that the Abbrevio is a hundred percent</p> <p>10 adjustable?</p> <p>11 A I don't understand that.</p> <p>12 Q Do you think a sling such as the Abbrevio,</p> <p>13 which is a hundred percent adjustable, is a</p> <p>14 potential clinical benefit over a sling</p> <p>15 which is not adjustable, such as the TVT?</p> <p>16 MS. VAN STEENBURGH: Object to</p> <p>17 form.</p> <p>18 THE WITNESS: I can't answer</p> <p>19 that, because I don't remember what -- I</p> <p>20 don't understand what "a hundred percent</p> <p>21 adjustable" means.</p> <p>22 BY MR. FAES:</p> <p>23 Q Did you understand what "a hundred percent</p> <p>24 adjustable" meant when you signed this form</p>
<p style="text-align: right;">Page 119</p> <p>1 the TVT Abbrevio; right?</p> <p>2 A Yeah. You see that it's not checked off.</p> <p>3 Q So, when you signed this document, did you</p> <p>4 believe that you were stating that you</p> <p>5 believed that this was a potential clinical</p> <p>6 benefit, that there would be less tissue</p> <p>7 dissection and 83 percent less mesh in the</p> <p>8 adductor muscles or not?</p> <p>9 A I cannot recall signing it, but I can recall</p> <p>10 that that was the theory when this thing</p> <p>11 came out.</p> <p>12 Q And you'd agree that if those theories are</p> <p>13 true, that that's a clinical benefit to</p> <p>14 patients; right?</p> <p>15 A That could be.</p> <p>16 Q If that's true, that would make the Abbrevio</p> <p>17 device a safer alternative than the TVT-O;</p> <p>18 right?</p> <p>19 MS. VAN STEENBURGH: Object to</p> <p>20 form.</p> <p>21 THE WITNESS: I can't answer</p> <p>22 that.</p> <p>23 BY MR. FAES:</p> <p>24 Q If a product has a clinical benefit over a</p>	<p style="text-align: right;">Page 121</p> <p>1 in 2010?</p> <p>2 A No. And it's not checked off, either. I</p> <p>3 don't think I signed that. It's just on the</p> <p>4 form.</p> <p>5 Q So, when you signed this form, you didn't</p> <p>6 have an understanding that you were agreeing</p> <p>7 with the statements in this document?</p> <p>8 A I can't recall.</p> <p>9 Q Before you signed this form, if there were</p> <p>10 anything that you disagreed with, you could</p> <p>11 have requested that it be taken off or be</p> <p>12 changed; correct?</p> <p>13 A It is not checked off, so essentially it is</p> <p>14 off. You have to check it to agree with it,</p> <p>15 and I had not checked it. So, that's all I</p> <p>16 can say.</p> <p>17 Q So, you believe that you did not agree to</p> <p>18 the statements on this form when you signed</p> <p>19 it in 2010 because it's not checked off?</p> <p>20 MS. VAN STEENBURGH: Object to</p> <p>21 form.</p> <p>22 THE WITNESS: I can't recall.</p> <p>23 What I see on the form that's in front of me,</p> <p>24 it is not checked off. So, therefore, I have</p>

<p style="text-align: right;">Page 122</p> <p>1 to assume that -- I don't know why it isn't</p> <p>2 checked off.</p> <p>3 BY MR. FAES:</p> <p>4 Q It also -- sorry.</p> <p>5 A Maybe I didn't agree with it. Maybe it was</p> <p>6 irrelevant. I can't remember.</p> <p>7 Q It also states that "Proven efficacy as</p> <p>8 TVT-O Abbrevio is launching with one year of</p> <p>9 Level One RCT data 97.7 success (compared in</p> <p>10 head to head study with our proven TVT-O</p> <p>11 sling)."</p> <p>12 Do you see that?</p> <p>13 A Yes. Same thing. It's not checked off. I</p> <p>14 can't speak to it, really.</p> <p>15 Q So, let me ask you this: As you sit here</p> <p>16 today, do you believe that the TVT Abbrevio</p> <p>17 requires less tissue dissection than the</p> <p>18 TVT-O device?</p> <p>19 A No. It's the same dissection.</p> <p>20 Q Would you agree that a device that does have</p> <p>21 less tissue dissection than the TVT-O, that</p> <p>22 that's a potential clinical benefit to the</p> <p>23 patient?</p> <p>24 A Yes.</p>	<p style="text-align: right;">Page 124</p> <p>1 actually true regarding the Abbrevio device,</p> <p>2 would you agree with me that you don't have</p> <p>3 any opinions, as you sit here today, as to</p> <p>4 whether or not the Abbrevio device is the</p> <p>5 safer alternative to the TVT-O?</p> <p>6 A That's correct.</p> <p>7 Q It also states that it's a hundred percent</p> <p>8 adjustable. I think I'll move on from that,</p> <p>9 because you said you don't even know what</p> <p>10 that means; right?</p> <p>11 A I don't know what it means. On the form, it</p> <p>12 looks like it's written by the salesperson.</p> <p>13 I can't answer that.</p> <p>14 Q So, you believe that this form was filled</p> <p>15 out by your sales representative, Laura</p> <p>16 Mettner?</p> <p>17 A Wasn't her name on it here somewhere?</p> <p>18 Q Actually, it is. "Manufacturer/Supplier</p> <p>19 Contact Name: Laura Mettner."</p> <p>20 MS. VAN STEENBURGH: Her name</p> <p>21 is right here (indicating).</p> <p>22 THE WITNESS: Yeah, I see that.</p> <p>23 It's a product request form. All I signed to</p> <p>24 is it's a TVT Abbrevio obturator sling for SUI</p>
<p style="text-align: right;">Page 123</p> <p>1 Q As you sit here today, do you believe that</p> <p>2 the TVT Abbrevio has 83 percent less mesh in</p> <p>3 the adductor muscles and 32 percent less</p> <p>4 mesh overall than the TVT-O?</p> <p>5 A I don't know. I see it's an unchecked thing</p> <p>6 on the form here. That's all I can say</p> <p>7 about it.</p> <p>8 Q So, as you sit here today, you don't know</p> <p>9 one way or the other whether it's true that</p> <p>10 the Abbrevio, when it's placed, has 83</p> <p>11 percent less mesh in the adductor muscles</p> <p>12 and 32 percent less mesh overall?</p> <p>13 A I don't know that. I just know that the</p> <p>14 Abbrevio is a shorter sling. It doesn't go</p> <p>15 all the way through the body. It goes</p> <p>16 partially through and then there's a suture.</p> <p>17 It has less mesh.</p> <p>18 Q So, would you agree that a mesh device which</p> <p>19 leaves 83 percent less mesh in the adductor</p> <p>20 muscles and 32 percent less mesh overall is</p> <p>21 a potential clinical benefit to patients</p> <p>22 receiving that device?</p> <p>23 A In theory.</p> <p>24 Q And since you don't know whether that's</p>	<p style="text-align: right;">Page 125</p> <p>1 in the hospital. All that information you</p> <p>2 asked me, I just can't answer it. I see her</p> <p>3 name on it. This was likely laid in front of</p> <p>4 me by a salesperson.</p> <p>5 BY MR. FAES:</p> <p>6 Q So, I guess my question was: Is it true</p> <p>7 that you believe that this form that you</p> <p>8 signed was likely filled out by a</p> <p>9 salesperson?</p> <p>10 A Yeah, I think so.</p> <p>11 Q And at any time did you tell that</p> <p>12 salesperson that you felt uncomfortable with</p> <p>13 any of the statements being made in this</p> <p>14 form before you signed it?</p> <p>15 A I cannot recall that.</p> <p>16 Q If you look under Other Impacts, it states,</p> <p>17 "Less inner thigh pain for patient."</p> <p>18 Do you see that?</p> <p>19 A In her statement?</p> <p>20 MS. VAN STEENBURGH: No, right</p> <p>21 here (indicating).</p> <p>22 BY MR. FAES:</p> <p>23 Q Under "Other Impacts" in the same section.</p> <p>24 A Yeah. That was a theory.</p>

<p style="text-align: right;">Page 126</p> <p>1 Q Would you agree that a device that results</p> <p>2 in less inner thigh pain for the patient is</p> <p>3 a potential clinical benefit for that</p> <p>4 patient?</p> <p>5 A That's correct. And that's why we wanted to</p> <p>6 try it.</p> <p>7 Q Do you have any opinions in this case as to</p> <p>8 whether or not the Abbrevio device does, in</p> <p>9 fact, result in less inner thigh pain for</p> <p>10 the patient than the TVT-O?</p> <p>11 A I don't.</p> <p>12 Q If you also look under the section where it</p> <p>13 states, "Is there a comparable</p> <p>14 product/procedure in the HealthEast system</p> <p>15 now? (i.e., What will this</p> <p>16 product/procedure be used in place of?)"</p> <p>17 And this box is checked "Yes." And it</p> <p>18 states, "If yes, explain. "TVT-O, Aris, and</p> <p>19 MiniArc."</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q Did you have an understanding at the time</p> <p>23 you signed this form that the Abbrevio</p> <p>24 device -- whether -- well, strike that. Let</p>	<p style="text-align: right;">Page 128</p> <p>1 Q Would you agree with me that you've never</p> <p>2 engaged in the study of whether or not the</p> <p>3 use of the TVT Abbrevio device results in</p> <p>4 less chronic pain syndromes for the patient</p> <p>5 than the use of the TVT-O device?</p> <p>6 A Right.</p> <p>7 Q Are you familiar with the term "chronic pain</p> <p>8 syndrome" as it relates to the TVT-O device?</p> <p>9 MS. VAN STEENBURGH: Object to</p> <p>10 form.</p> <p>11 THE WITNESS: No.</p> <p>12 BY MR. FAES:</p> <p>13 Q You've never read any literature by anyone</p> <p>14 describing chronic pain syndromes after</p> <p>15 placement of the TVT-O?</p> <p>16 MS. VAN STEENBURGH: Object to</p> <p>17 form.</p> <p>18 THE WITNESS: Yes. Yes, I have</p> <p>19 read about the pain, yes.</p> <p>20 BY MR. FAES:</p> <p>21 Q Do you believe that development of chronic</p> <p>22 pain syndromes as a result of the mesh being</p> <p>23 in the obturator space in the adductor</p> <p>24 muscles of the patient is a unique risk with</p>
<p style="text-align: right;">Page 127</p> <p>1 me ask a better question.</p> <p>2 Did you have an understanding, when</p> <p>3 you signed this form, whether or not the TVT</p> <p>4 Abbrevio device is considered a full-length</p> <p>5 sling or a mini sling, more like the Aris or</p> <p>6 MiniArc?</p> <p>7 A I can't remember my thinking when I signed</p> <p>8 this form, other than similar forms are once</p> <p>9 in a while in front of me if I want anything</p> <p>10 in the OR that isn't there. But I looked at</p> <p>11 the TVT Abbrevio as a full sling -- in</p> <p>12 between. It was neither a mini sling or a</p> <p>13 full sling. It was a shorter sling.</p> <p>14 Q Would you agree with me that you've never</p> <p>15 engaged in the study of whether or not the</p> <p>16 TVT Abbrevio device results in less inner</p> <p>17 thigh pain for the patient than the TVT-O?</p> <p>18 A That's correct.</p> <p>19 Q Would you agree with me that you've never</p> <p>20 engaged in the study of whether or not there</p> <p>21 is, in fact, less mesh with the Abbrevio</p> <p>22 device in the adductor muscles than the</p> <p>23 TVT-O device?</p> <p>24 A Correct.</p>	<p style="text-align: right;">Page 129</p> <p>1 the TVT-O as opposed to the TVT retropubic?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: I have to answer</p> <p>5 that in two parts. There's a big difference</p> <p>6 between the two slings, number one. Number</p> <p>7 two, most of the groin pain that I have</p> <p>8 experienced with the TVT-O sling has been</p> <p>9 temporary pain, not so much as chronic. I</p> <p>10 can't recall anyone I've seen with chronic</p> <p>11 pain from the TVT-O. If there are, they are</p> <p>12 few and far between. Temporary pain I've</p> <p>13 seen, and that's why we tried out the shorter</p> <p>14 sling.</p> <p>15 BY MR. FAES:</p> <p>16 Q So, is it your testimony that you never had</p> <p>17 an experience -- never had a patient that's</p> <p>18 experienced chronic pain with the TVT-O</p> <p>19 sling? And defining chronic pain as pain</p> <p>20 lasting a year or longer.</p> <p>21 A I can't say that. I can't recall anyone</p> <p>22 with chronic pain. But I can recall people</p> <p>23 with temporary pain.</p> <p>24 Q And do you know how many TVT-O devices</p>

<p style="text-align: right;">Page 130</p> <p>1 you've implanted over the course of your</p> <p>2 career? Do you have an approximation?</p> <p>3 A No.</p> <p>4 Q And you don't know how many TVT retropubic</p> <p>5 devices you've implanted over the course of</p> <p>6 your career?</p> <p>7 A No.</p> <p>8 Q What about TVT-Exact?</p> <p>9 A No.</p> <p>10 Q When's the last time you excised or removed</p> <p>11 a TVT or TVT-O mesh?</p> <p>12 A About a month ago.</p> <p>13 Q And what was the -- first of all, do you</p> <p>14 remember if it was a TVT or TVT-O?</p> <p>15 A It was a TVT.</p> <p>16 Q What was the indications for removal?</p> <p>17 A She had leukemia and she had an abscess</p> <p>18 formation, and she wasn't able to fight it,</p> <p>19 because she didn't have enough blood cells</p> <p>20 to fight it. So, we ended up having to go</p> <p>21 in and remove the sling to help fight the</p> <p>22 infection.</p> <p>23 Q So, the indication for removal was an</p> <p>24 abscess?</p>	<p style="text-align: right;">Page 132</p> <p>1 vaginal canal?</p> <p>2 MR. FAES: I mean exposed or</p> <p>3 extruded anywhere.</p> <p>4 THE WITNESS: Sling or --</p> <p>5 MS. VAN STEENBURGH: He's</p> <p>6 talking about sling.</p> <p>7 BY MR. FAES:</p> <p>8 Q Actually, first, let's talk about all</p> <p>9 meshes, all pelvic meshes.</p> <p>10 A What's the question?</p> <p>11 Q What are some of the indications, besides it</p> <p>12 being in the wrong place, where you've had</p> <p>13 to remove or revise a pelvic mesh that was</p> <p>14 not either exposed or extruded?</p> <p>15 A Too tight --</p> <p>16 MS. VAN STEENBURGH: Just a</p> <p>17 second. Object to form. I think his</p> <p>18 testimony was it was placed in the wrong</p> <p>19 place, not that it was just in the wrong</p> <p>20 place.</p> <p>21 Go ahead.</p> <p>22 THE WITNESS: Too tight. Too</p> <p>23 loose. Pain.</p> <p>24</p>
<p style="text-align: right;">Page 131</p> <p>1 A Yes.</p> <p>2 Q Have you ever had to excise or remove or --</p> <p>3 that's a bad question.</p> <p>4 Have you ever had to excise or remove</p> <p>5 or cut -- actually, let me ask you two</p> <p>6 different questions, make it less confusing.</p> <p>7 Have you ever had to excise, or</p> <p>8 remove, a mesh that was not actually exposed</p> <p>9 or extruded?</p> <p>10 A Yes.</p> <p>11 Q What were the indications for the excision</p> <p>12 or removals when the mesh wasn't actually</p> <p>13 eroded or exposed?</p> <p>14 A Different -- different cases.</p> <p>15 Q What are some of the indications for</p> <p>16 excision or removal of a mesh where the mesh</p> <p>17 is not actually exposed or extruded?</p> <p>18 A The mesh has been placed in the wrong place.</p> <p>19 Q Is that the only indication for removing a</p> <p>20 mesh --</p> <p>21 A No.</p> <p>22 Q -- that's not exposed? Sorry.</p> <p>23 MS. VAN STEENBURGH: And when</p> <p>24 you say not "exposed," you mean in the</p>	<p style="text-align: right;">Page 133</p> <p>1 BY MR. FAES:</p> <p>2 Q Any others?</p> <p>3 A Or not placed right.</p> <p>4 Q So, you'd agree that there are situations</p> <p>5 where -- strike that.</p> <p>6 Are there situations where you've had</p> <p>7 to excise or remove a pelvic mesh where the</p> <p>8 only indication for removal was pain?</p> <p>9 A Yes.</p> <p>10 Q And how many times --</p> <p>11 A Let me answer that again. That's the only</p> <p>12 indication was pain?</p> <p>13 Q Yes.</p> <p>14 A Yes, it has happened.</p> <p>15 (Exhibit No. 12 Marked.)</p> <p>16</p> <p>17 BY MR. FAES:</p> <p>18 Q Doctor, I'm going to hand you what's been</p> <p>19 marked as Exhibit No. 12 to your deposition.</p> <p>20 This is an e-mail string dated February 2nd</p> <p>21 of 2012. And this is regarding the meeting</p> <p>22 that you went to in Florida regarding the</p> <p>23 Artisyn mesh.</p> <p>24 Do you remember talking about that?</p>

<p style="text-align: right;">Page 134</p> <p>1 A Uh-huh.</p> <p>2 Q And actually, if you can turn to, I think,</p> <p>3 what is the third page which is where the</p> <p>4 string starts, and the string starts with an</p> <p>5 e-mail from Brian Luscombe to you on January</p> <p>6 30th, 2012.</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q First of all, do you remember who Brian</p> <p>10 Luscombe is?</p> <p>11 A I can't remember right now.</p> <p>12 Q Do you remember when the last time you had</p> <p>13 contact with him was?</p> <p>14 A I can't remember that, either.</p> <p>15 Q And you can see that he copied your sales</p> <p>16 rep at the time, which was Laura Mettner.</p> <p>17 You do know and remember her; right?</p> <p>18 A Yes. Laura Mettner.</p> <p>19 Q Yes. And it starts, "Dear Dr. Mjanger, I am</p> <p>20 hoping to touch base with you regarding your</p> <p>21 possible participation in a commercial</p> <p>22 advisory board (including a cadaver lab with</p> <p>23 robot particular and straight-stick</p> <p>24 stations) being held by Ethicon Women's</p>	<p style="text-align: right;">Page 136</p> <p>1 31st, "I can go to Florida. Ron Mjanger."</p> <p>2 Right?</p> <p>3 A Yes.</p> <p>4 Q And so, you agreed to participate in this</p> <p>5 commercial advisory board --</p> <p>6 A Yes.</p> <p>7 Q -- for the Artisyn product and you received</p> <p>8 \$3300 plus travel and room for that event;</p> <p>9 right?</p> <p>10 A That's correct.</p> <p>11 Q What was your understanding, when you</p> <p>12 accepted this invitation, of what your</p> <p>13 duties and responsibilities would be when</p> <p>14 you went to this event?</p> <p>15 MS. VAN STEENBURGH: Objection,</p> <p>16 asked and answered.</p> <p>17 Go ahead.</p> <p>18 THE WITNESS: They asked me if</p> <p>19 I would come down to Florida and participate</p> <p>20 in a cadaver lab. They invited surgeons from</p> <p>21 around the country and they had this new Y</p> <p>22 mesh which they came fairly late to market</p> <p>23 with and they wanted us to put it in a</p> <p>24 cadaver and then answer some questions, if we</p>
<p style="text-align: right;">Page 135</p> <p>1 Health & Urology."</p> <p>2 Do you see that?</p> <p>3 A Yes.</p> <p>4 Q And it states, "The purpose of this meeting</p> <p>5 is to gather thought-leading surgeons from</p> <p>6 around the U.S. who are experts in</p> <p>7 laparoscopic sacrocolpopexy to discuss</p> <p>8 surgical techniques and to evaluate a new</p> <p>9 product that we currently have under</p> <p>10 development."</p> <p>11 Do you see that?</p> <p>12 A Yes.</p> <p>13 Q And it states that you would receive an</p> <p>14 honorarium for your participation in this</p> <p>15 event.</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q And it states that the honoraria that you</p> <p>19 would receive would be \$3300, plus travel</p> <p>20 and room.</p> <p>21 Do you see that?</p> <p>22 A Right.</p> <p>23 Q And if you look higher up on the page, it</p> <p>24 looks like you replied on Tuesday, January</p>	<p style="text-align: right;">Page 137</p> <p>1 liked it or didn't like it. And they wanted</p> <p>2 us to be honest and tell them anything that</p> <p>3 we wanted to tell them. And I was asked to</p> <p>4 use laparoscopic technique to do that</p> <p>5 sacrocolpopexy on a cadaver. The person next</p> <p>6 to me did robotic insertion. There was a</p> <p>7 whole room full of us. We all switched</p> <p>8 around and we all tried it and then we went</p> <p>9 into a conference room and there were</p> <p>10 engineers and developers from the company</p> <p>11 asking us what we thought about it.</p> <p>12 We basically slaughtered them. We</p> <p>13 told them what we thought about it. They</p> <p>14 asked if we would think of switching from</p> <p>15 the product we used to that product. I</p> <p>16 don't think it went very well for Ethicon.</p> <p>17 It was just to give an honest opinion about</p> <p>18 what the product felt like, what it looked</p> <p>19 like. Would you quit using Restorelle to</p> <p>20 use this? And I said no.</p> <p>21 BY MR. FAES:</p> <p>22 Q Did you say you don't think it went very</p> <p>23 well for Ethicon?</p> <p>24 A No. They told us to give them our honest</p>

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<p>1 opinion and everybody did. They said,</p> <p>2 "Don't you have anything good to say about</p> <p>3 us?" You asked us to be honest. And it was</p> <p>4 not an education. It was not sales. They</p> <p>5 just wanted to show us their product and say</p> <p>6 what we thought about the product.</p> <p>7 What was discussed was the mesh and</p> <p>8 the feel and the color and the shape. These</p> <p>9 are surgeons like me that were using a</p> <p>10 product already.</p> <p>11 Q And was this the only commercial advisory</p> <p>12 board that you ever participated in with</p> <p>13 Ethicon and Johnson & Johnson?</p> <p>14 A Yes, yes.</p> <p>15 I don't know if the product went to</p> <p>16 market after that or not. I know they came</p> <p>17 out with a Y mesh later.</p> <p>18 MS. VAN STEENBURGH: There's no</p> <p>19 -- he hasn't asked you a question.</p> <p>20 THE WITNESS: Sorry.</p> <p>21 MR. FAES: No. But I'm loving</p> <p>22 it.</p> <p>23 BY MR. FAES:</p> <p>24 Q So, before your counsel stopped you there,</p>	<p>1 (Exhibit No. 13 Marked.)</p> <p>2</p> <p>3 BY MR. FAES:</p> <p>4 Q Doctor, I'm going to hand you what's been</p> <p>5 marked as Exhibit No. 13 to your deposition.</p> <p>6 And this is a document that states at the</p> <p>7 top "Pendix II, Surgeon Questionnaire." And</p> <p>8 the evaluator name at the top, it states</p> <p>9 "Ron Mjanger."</p> <p>10 Do you see that?</p> <p>11 A Right.</p> <p>12 Q And it states the evaluator signature and</p> <p>13 date was March 11th of 2012. And if you</p> <p>14 look at the location, it's Orlando Hospital,</p> <p>15 Florida. And the nature of the procedure is</p> <p>16 sacrocolpopexy.</p> <p>17 A Yes.</p> <p>18 Q Does this appear to be the form that you</p> <p>19 would have filled out at that commercial</p> <p>20 meeting in Florida in February of 2012?</p> <p>21 A Uh-huh. Yeah.</p> <p>22 Q And I want to ask you about some of the</p> <p>23 comments that it looks like you made on the</p> <p>24 very last page. If you can turn to the very</p>
Page 139	Page 141
<p>1 you stated that you don't know whether or</p> <p>2 not the Artisyn Y mesh actually went to</p> <p>3 market or not; is that correct?</p> <p>4 A I know they have a product. I don't know</p> <p>5 much about it. I haven't used it.</p> <p>6 Q Do you recall being asked several months</p> <p>7 later by sales reps for Ethicon and Johnson</p> <p>8 & Johnson to try to get you to use that in</p> <p>9 your practice?</p> <p>10 A I can't remember that.</p> <p>11 Q And at this commercial advisory board that</p> <p>12 you participated at with Ethicon in January</p> <p>13 of 2012, you -- we talked about you gave</p> <p>14 them your honest feedback.</p> <p>15 Do you remember giving them --</p> <p>16 filling out a written evaluation form on the</p> <p>17 Artisyn mesh?</p> <p>18 A I can't remember that.</p> <p>19 Q If you did fill out a written evaluation</p> <p>20 form regarding the Artisyn mesh, would you</p> <p>21 have been truthful and accurate in your</p> <p>22 feedback to Ethicon and Johnson & Johnson</p> <p>23 regarding the mesh?</p> <p>24 A I would think so.</p>	<p>1 last page of the document.</p> <p>2 A (Complying.)</p> <p>3 Q It's page 8 of 8.</p> <p>4 A Okay.</p> <p>5 Q And it states "Comments/Observation Sheet."</p> <p>6 It states "Dr. Mjanger also thought that the</p> <p>7 stiffness of the mesh was important for the</p> <p>8 sacral edge that is plase [sic] to the</p> <p>9 arteries (pulsing) and prefers to leave very</p> <p>10 soft material in this area."</p> <p>11 Do you see that?</p> <p>12 A Yes.</p> <p>13 Q Is that feedback that you gave to Ethicon</p> <p>14 and Johnson & Johnson regarding the vaginal</p> <p>15 mesh --</p> <p>16 A Right.</p> <p>17 Q -- that you evaluated in February?</p> <p>18 A Right.</p> <p>19 Q Would you agree that stiffness of mesh is</p> <p>20 very important when you're placing surgical</p> <p>21 mesh anywhere in the pelvic floor or pelvic</p> <p>22 area?</p> <p>23 A Not anywhere.</p> <p>24 Q When is it not important? When is stiffness</p>

<p style="text-align: right;">Page 142</p> <p>1 not important?</p> <p>2 A I didn't like the stiffness here. That's</p> <p>3 what I'm saying here.</p> <p>4 Q Right. So, you would agree that if a mesh</p> <p>5 is too stiff, you don't want to have that</p> <p>6 edge too close to arteries, because it can</p> <p>7 cause --</p> <p>8 A Right.</p> <p>9 Q -- irritation or problems; right?</p> <p>10 MS. VAN STEENBURGH: Object to</p> <p>11 form.</p> <p>12 THE WITNESS: Right.</p> <p>13 BY MR. FAES:</p> <p>14 Q And in general, you prefer to have very soft</p> <p>15 material in the vaginal area when you're</p> <p>16 placing mesh?</p> <p>17 MS. VAN STEENBURGH: Object to</p> <p>18 form.</p> <p>19 THE WITNESS: Yes, yes.</p> <p>20 BY MR. FAES:</p> <p>21 Q Would you agree that it's possible for a</p> <p>22 mesh to be too stiff for placement in a</p> <p>23 woman's vaginal tissues?</p> <p>24 MS. VAN STEENBURGH: Object to</p>	<p style="text-align: right;">Page 144</p> <p>1 patient?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: Yes, yes.</p> <p>5 BY MR. FAES:</p> <p>6 Q You stated earlier that you felt that soft</p> <p>7 mesh was an advantage.</p> <p>8 Did I hear you right?</p> <p>9 MS. VAN STEENBURGH: Object to</p> <p>10 form.</p> <p>11 THE WITNESS: In some</p> <p>12 situations.</p> <p>13 BY MR. FAES:</p> <p>14 Q In what situations is it advantageous to</p> <p>15 have a very soft mesh?</p> <p>16 A What I stated on this form. It goes right</p> <p>17 back to it, that stiffness of the mesh line</p> <p>18 up against pulsating vessels. I don't like</p> <p>19 that. I like soft mesh. That's why I made</p> <p>20 this comment right here that we started</p> <p>21 with.</p> <p>22 Q So, are there any other situations where</p> <p>23 it's advantageous to have a soft mesh?</p> <p>24 MS. VAN STEENBURGH: Object to</p>
<p style="text-align: right;">Page 143</p> <p>1 form.</p> <p>2 THE WITNESS: What mesh are you</p> <p>3 talking about?</p> <p>4 BY MR. FAES:</p> <p>5 Q I'm not talking about any specific mesh.</p> <p>6 I'm just saying as a general concept, would</p> <p>7 you agree that it's possible that a surgical</p> <p>8 mesh can be too stiff to be safely placed in</p> <p>9 a woman's vaginal tissues for stress urinary</p> <p>10 incontinence?</p> <p>11 A I don't think I would say "safely." It's an</p> <p>12 advantage to have soft mesh for the vagina.</p> <p>13 "Safely," I don't think I would say.</p> <p>14 Q So, you don't think that if the mesh is</p> <p>15 potentially too stiff or stiffer than other</p> <p>16 products, it can't potentially cause more</p> <p>17 erosions or pain for the patient?</p> <p>18 A What mesh are you talking about?</p> <p>19 Q I'm not talking about any mesh specifically.</p> <p>20 I'm just talking about in general, would you</p> <p>21 agree that it's possible that a mesh can be</p> <p>22 too stiff for placement for stress urinary</p> <p>23 incontinence and the use of that stiff mesh</p> <p>24 could potentially cause more erosions for a</p>	<p style="text-align: right;">Page 145</p> <p>1 form.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. FAES:</p> <p>4 Q What are those situations?</p> <p>5 A I like soft mesh when I do sacrocolpopexy.</p> <p>6 Q So, we talked about what situations it's</p> <p>7 advantageous to have a soft mesh. What are</p> <p>8 the advantages to the physician and the</p> <p>9 patient of a soft mesh?</p> <p>10 MS. VAN STEENBURGH: In a</p> <p>11 sacrocolpopexy. That's what he said.</p> <p>12 THE WITNESS: It feels good.</p> <p>13 It doesn't poke against arteries.</p> <p>14 BY MR. FAES:</p> <p>15 Q Do you feel that there are situations where</p> <p>16 it's advantageous to have a soft mesh for</p> <p>17 stress urinary incontinence?</p> <p>18 A I don't remember that being an issue in</p> <p>19 stress urinary incontinence. I don't think</p> <p>20 we've had obstacles there. I don't know how</p> <p>21 to answer that.</p> <p>22 Q Have you --</p> <p>23 MR. FAES: Can you read back</p> <p>24 his answer?</p>

<p style="text-align: right;">Page 146</p> <p>1 (The record was read as requested.)</p> <p>2 BY MR. FAES:</p> <p>3 Q So, have you ever evaluated any mesh that</p> <p>4 you felt was a soft mesh for a stress</p> <p>5 urinary incontinence?</p> <p>6 A In a study?</p> <p>7 Q In a study or anywhere.</p> <p>8 A No.</p> <p>9 Q So, is it your opinion that all of the</p> <p>10 meshes that you've ever evaluated for the</p> <p>11 treatment of stress urinary incontinence are</p> <p>12 not stiff?</p> <p>13 MS. VAN STEENBURGH: Object to</p> <p>14 form.</p> <p>15 BY MR. FAES:</p> <p>16 Q Strike that.</p> <p>17 So, is it your opinion that all of</p> <p>18 the meshes that you've evaluated for stress</p> <p>19 urinary incontinence are not soft?</p> <p>20 MS. VAN STEENBURGH: Object to</p> <p>21 form.</p> <p>22 THE WITNESS: I haven't done</p> <p>23 any evaluation of the soft versus hard mesh.</p> <p>24</p>	<p style="text-align: right;">Page 148</p> <p>1 missing the word "surprised." Is it there?</p> <p>2 MR. FAES: "...and was</p> <p>3 surprised that it would not unravel."</p> <p>4 BY MR. FAES:</p> <p>5 Q I'm reading right here (indicating).</p> <p>6 A (Witness reviews the document.)</p> <p>7 You want my comment about that?</p> <p>8 Q So, my question is: That was a feedback</p> <p>9 that you gave during this evaluation, is</p> <p>10 that you cut the Artisyn mesh along the seam</p> <p>11 and was surprised that it would not unravel.</p> <p>12 First of all, is that correct, that</p> <p>13 that was feedback that you gave?</p> <p>14 A Yeah, that's the feedback that I gave.</p> <p>15 MS. VAN STEENBURGH: Objection</p> <p>16 to form. Go ahead.</p> <p>17 THE WITNESS: All of this is</p> <p>18 feedback I gave. I know what it means, too.</p> <p>19 BY MR. FAES:</p> <p>20 Q So, the follow-up question is: Why were you</p> <p>21 surprised that when you cut along the seam,</p> <p>22 that the mesh wouldn't unravel?</p> <p>23 A It was a mesh that had one string going</p> <p>24 across creating that Y flap. And when we</p>
<p style="text-align: right;">Page 147</p> <p>1 BY MR. FAES:</p> <p>2 Q So, you'd agree then since you haven't done</p> <p>3 any evaluations of any hard versus soft mesh</p> <p>4 for the treatment of stress urinary</p> <p>5 incontinence, you have no opinions as to</p> <p>6 whether a softer mesh would be a safer</p> <p>7 alternative design to the mesh used in the</p> <p>8 TVT and TVT-O?</p> <p>9 A That's correct.</p> <p>10 Q If you look down under "Comments and</p> <p>11 Intraoperative Sheet," it looks like you cut</p> <p>12 the mesh and placed a suture on the sacral</p> <p>13 flap for orientation, trimmed the mesh on</p> <p>14 both anterior and posterior side, did not</p> <p>15 round the edges. "He cut the seam and was</p> <p>16 surprised that it would not unravel."</p> <p>17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q So, you gave feedback that when you cut this</p> <p>20 Artisyn mesh on the seam, that you were</p> <p>21 surprised that it didn't unravel?</p> <p>22 A Let me read that.</p> <p>23 (Witness reviews the document.)</p> <p>24 MS. VAN STEENBURGH: I'm</p>	<p style="text-align: right;">Page 149</p> <p>1 trimmed it narrower, cut that one string and</p> <p>2 the whole thing would fall apart.</p> <p>3 This one here was made in a different</p> <p>4 way so that I could trim the width down and</p> <p>5 it didn't fall apart. That was an</p> <p>6 advantage.</p> <p>7 Q Right. So, you've encountered other meshes</p> <p>8 in the past where if you cut along the seam,</p> <p>9 it would unravel?</p> <p>10 A Not along the seam. You would make it</p> <p>11 narrower. Like a Band-Aid. You cut it off</p> <p>12 and make it narrower.</p> <p>13 Q Okay. So, you had experience with other</p> <p>14 meshes where when you've cut the mesh, it</p> <p>15 would unravel?</p> <p>16 A Yeah. You couldn't trim it. This one you</p> <p>17 could trim. I think it was an AMS you</p> <p>18 couldn't trim. This one you can trim.</p> <p>19 Q So, you'd agree that a mesh that becomes</p> <p>20 unraveled is a potential safety concern for</p> <p>21 a patient; right?</p> <p>22 MS. VAN STEENBURGH: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: No, no. We're</p>

<p style="text-align: right;">Page 150</p> <p>1 not talking about the same thing. When you</p> <p>2 try to narrow the mesh, the older kind that I</p> <p>3 used, it was destroyed. So, I was prevented</p> <p>4 from making it narrower for a smaller person.</p> <p>5 This one here had an advantage that I could</p> <p>6 take the mesh strip like this (indicating)</p> <p>7 and I could take my scissor and cut off the</p> <p>8 side without the Y part of it falling apart.</p> <p>9 So, it has nothing to do with</p> <p>10 unraveling mesh. It had to do with a suture</p> <p>11 that was used to hold it together. It was</p> <p>12 the way it was sewed together.</p> <p>13 So, this one here (indicating), I can</p> <p>14 cut to different sizes, while the old one</p> <p>15 you couldn't. So, that was considered an</p> <p>16 advantage.</p> <p>17 BY MR. FAES:</p> <p>18 Q So, I guess my follow-up question is: You'd</p> <p>19 agree with me that you wouldn't want to use</p> <p>20 a mesh that might become unraveled after it</p> <p>21 was placed in the patient; right?</p> <p>22 MS. VAN STEENBURGH: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: Yeah.</p>	<p style="text-align: right;">Page 152</p> <p>1 form.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. FAES:</p> <p>4 Q You'd agree that a mesh that becomes curled</p> <p>5 up could be a clinical concern for the</p> <p>6 patient; right?</p> <p>7 A Yes.</p> <p>8 Q You'd agree that a mesh that becomes curled</p> <p>9 up can be a clinical concern for the patient</p> <p>10 regardless of whether it's used for SUI or</p> <p>11 pelvic organ prolapse; right?</p> <p>12 MS. VAN STEENBURGH: Object to</p> <p>13 form.</p> <p>14 THE WITNESS: Disagree.</p> <p>15 BY MR. FAES:</p> <p>16 Q So, you don't agree that a mesh that becomes</p> <p>17 curled up for stress urinary incontinence</p> <p>18 has any potential to cause any kind of</p> <p>19 adverse clinical outcomes for a patient?</p> <p>20 MS. VAN STEENBURGH: Object to</p> <p>21 form.</p> <p>22 THE WITNESS: You're talking</p> <p>23 about two totally different situations and</p> <p>24 different things.</p>
<p style="text-align: right;">Page 151</p> <p>1 BY MR. FAES:</p> <p>2 Q Okay. Another feedback that you gave --</p> <p>3 actually, let me back up.</p> <p>4 You said that an earlier mesh that</p> <p>5 you cut would become unraveled.</p> <p>6 What mesh were you referring to?</p> <p>7 A I can't recall for sure, but I think it was</p> <p>8 AMS.</p> <p>9 Q Okay. An AMS Y-Mesh, do you think?</p> <p>10 A Yes.</p> <p>11 Q Like an IntePro Y-Mesh?</p> <p>12 A I can't remember. I know there was a Y mesh</p> <p>13 that couldn't be trimmed. You would cut a</p> <p>14 suture out of it. It was sewn together.</p> <p>15 Q Okay. And the next feedback you give is</p> <p>16 that "During sewing, [you] complained that</p> <p>17 the mesh curled up (edges) and it would be a</p> <p>18 concern for the bladder (irritation)."</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q And that was a feedback that you gave</p> <p>22 regarding this vaginal mesh prototype that</p> <p>23 you were evaluating; correct?</p> <p>24 MS. VAN STEENBURGH: Object to</p>	<p style="text-align: right;">Page 153</p> <p>1 BY MR. FAES:</p> <p>2 Q I am.</p> <p>3 A Yes. This mesh, when you sew it to the</p> <p>4 vagina, if you put the stitches close to the</p> <p>5 edge, it rises the cut edge and that can</p> <p>6 irritate the outside of the bladder. When</p> <p>7 you deal with a sling, there's no stitches,</p> <p>8 there's no sewing. That phenomenon doesn't</p> <p>9 exist with a sling.</p> <p>10 Q So, you've never seen any kind of reports in</p> <p>11 the clinical literature of a sling becoming</p> <p>12 curled and causing adverse outcomes for a</p> <p>13 patient?</p> <p>14 A I have never seen or heard about anyone</p> <p>15 sewing into the sling rising the edge.</p> <p>16 That's what I'm talking about in the Y mesh.</p> <p>17 Sewing a seam close to the edge curling the</p> <p>18 edge up, that wouldn't happen with a sling,</p> <p>19 because we're never sewing a sling.</p> <p>20 Q I understand that. But you'd agree that</p> <p>21 irrespective of whether a -- strike that.</p> <p>22 With a sling, there's no sewing of</p> <p>23 the sling with a suture; right?</p> <p>24 A Right.</p>

<p style="text-align: right;">Page 154</p> <p>1 Q But if that sling were to become curled up, 2 it could also cause a clinical concern for 3 the patient; right? 4 MS. VAN STEENBURGH: Object to 5 form. 6 THE WITNESS: Never seen it 7 curl up. We're talking about two completely 8 different phenomenons. 9 BY MR. FAES: 10 Q I just want to make sure your testimony is 11 clear on this. 12 You're not aware and you've never 13 seen any reports in the clinical literature 14 of a sling becoming curled up and causing 15 clinical problems for a patient? 16 A What do you mean with "curled up"? I don't 17 understand the question. I don't understand 18 what a "curled up" sling is. Slings are 19 taped. Here we're talking about sewing. I 20 don't see the connection. I don't 21 understand the question. 22 Q I know. Let's forget about this document 23 for a minute. 24 I'm asking, have you ever seen --</p>	<p style="text-align: right;">Page 156</p> <p>1 becoming rolled or curled up? 2 A Rolled is a different story. I just don't 3 get it. Pulling on a sling -- a sling 4 doesn't curl up by itself. Someone is doing 5 something to it. It's a -- if someone 6 overstretched it or put it in wrong, you can 7 destroy it. I've seen that. 8 Q Okay. So, you have seen instances where a 9 sling has been curled up? 10 A I've seen a sling damaged. I wouldn't call 11 it "curled up." 12 Q Would you call it "rolled up"? 13 A It looks like it's rolled up. You take it 14 between your hands and pull it. Instead of 15 flat, it becomes round. 16 Q So, is it your opinion that the only way 17 that a mesh sling like the TVT can become 18 rolled up or curled is if someone puts too 19 much tension or force on the tape? 20 A Yeah, I believe so. 21 Q So, in any case where the -- where a sling 22 is found to be rolled or curled up, you 23 believe that the physician did that 24 procedure incorrectly?</p>
<p style="text-align: right;">Page 155</p> <p>1 first of all, let's break it down. 2 Are you aware or have you ever seen, 3 either in your clinical practice or reported 4 in the medical literature or in documents 5 you've reviewed from Ethicon and Johnson & 6 Johnson, reports of an SUI sling, like the 7 TVT, becoming curled up? 8 MS. VAN STEENBURGH: Object to 9 form. 10 THE WITNESS: Explain to me 11 what "curled up" means. I just don't know 12 what that means. I see fraying. I see 13 roping from overstressing a sling. Curling 14 up I don't understand. 15 BY MR. FAES: 16 Q You don't know what the word "curled" means? 17 A No. I don't see it curl. If you pull on 18 it, it may look like it's curled. It's from 19 overstressing. I haven't seen a sling curl 20 up, no. 21 Q So, you've never seen, either in the medical 22 literature, your clinical practice, or in 23 documents from Ethicon and Johnson & 24 Johnson, any reports of any mesh sling</p>	<p style="text-align: right;">Page 157</p> <p>1 MS. VAN STEENBURGH: Object to 2 form. 3 THE WITNESS: I believe there's 4 been too much tension. There's been an 5 attempt to adjust it after the sleeve is 6 pulled out. 7 BY MR. FAES: 8 Q And subjecting -- 9 A If you don't pull on it, it doesn't pull 10 itself. 11 Q So, do you believe that if you subject a 12 sling to too much tension, you've done the 13 sling incorrectly? 14 A Yes. 15 Q How much tension do you believe you can 16 apply to a sling in order for it to still be 17 done correctly? 18 A You can slide the sling up and down as long 19 as it is inside the sleeve. The minute the 20 sleeve is gone, it's done. If you pull it 21 down, you destroy it. 22 Q When you say "sleeve," just to make sure 23 we're on the same page, you mean the clear 24 plastic sleeve that's over the mesh; right?</p>

<p style="text-align: right;">Page 158</p> <p>1 A Yes.</p> <p>2 Q So, you believe that if you put any kind of</p> <p>3 force on the sling once the sheaths are</p> <p>4 removed, you're doing the procedure</p> <p>5 incorrectly?</p> <p>6 MS. VAN STEENBURGH: Objection.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. FAES:</p> <p>9 Q Even when you have the sling, when you</p> <p>10 implant it, there's actually a little</p> <p>11 section of the mesh, the part that goes</p> <p>12 underneath the urethra, that's never covered</p> <p>13 by the sleeve; right?</p> <p>14 A Right.</p> <p>15 Q Are you familiar with the Babcock technique</p> <p>16 at all for --</p> <p>17 A Absolutely, absolutely.</p> <p>18 Q Okay. So, have you ever seen procedure</p> <p>19 videos from Ethicon and Johnson & Johnson</p> <p>20 where they place a Babcock on the piece of</p> <p>21 the mesh that's not covered by the</p> <p>22 sheaths --</p> <p>23 A Yes.</p> <p>24 Q -- and then tension the mesh?</p>	<p style="text-align: right;">Page 160</p> <p>1 the sling.</p> <p>2 Q So, if, hypothetically, Ethicon did produce</p> <p>3 an educational procedure video showing that</p> <p>4 the TVT was to be done in that manner, you</p> <p>5 believe that they would be instructing</p> <p>6 physicians incorrectly?</p> <p>7 A I would like to see that before I make an</p> <p>8 opinion about the video.</p> <p>9 Q And I see that you state that your</p> <p>10 preference is for a very light mesh.</p> <p>11 Do you see that?</p> <p>12 A Correct.</p> <p>13 Q And is that accurate feedback that she gave</p> <p>14 regarding the use of this product?</p> <p>15 A I don't understand the question.</p> <p>16 Q I'll strike that.</p> <p>17 And it states that you characterized</p> <p>18 the Artisyn product as "stiff."</p> <p>19 Do you see that?</p> <p>20 A Yes.</p> <p>21 Q Did you feel that this mesh was too stiff</p> <p>22 for its intended use?</p> <p>23 MS. VAN STEENBURGH: Object to</p> <p>24 form.</p>
<p style="text-align: right;">Page 159</p> <p>1 A It has to be in the sleeve. If the sleeve</p> <p>2 is out, you can reach up on the sides with a</p> <p>3 Babcock or whatever and pull it down a</p> <p>4 little bit.</p> <p>5 Q So, have you ever seen any procedure videos</p> <p>6 for the TVT that were produced by Ethicon</p> <p>7 and Johnson & Johnson --</p> <p>8 A Yes.</p> <p>9 Q -- where they did exactly that. They placed</p> <p>10 the Babcock on the portion of the mesh that</p> <p>11 was not covered by the sleeves and put</p> <p>12 tension on it?</p> <p>13 A I can't recall that right now.</p> <p>14 Q But if there were such a video, you think</p> <p>15 that would be an incorrect way to teach</p> <p>16 someone how to do the TVT procedure because</p> <p>17 you're putting pressure on the mesh?</p> <p>18 MS. VAN STEENBURGH: Object to</p> <p>19 form.</p> <p>20 THE WITNESS: Are you talking</p> <p>21 about pulling right below the urethra?</p> <p>22 BY MR. FAES:</p> <p>23 Q Yes.</p> <p>24 A That would be incorrect. That would damage</p>	<p style="text-align: right;">Page 161</p> <p>1 THE WITNESS: Say that again.</p> <p>2 BY MR. FAES:</p> <p>3 Q Did you feel that this Artisyn mesh that you</p> <p>4 were evaluating was too stiff for its</p> <p>5 intended use?</p> <p>6 A No. I just liked the other one better.</p> <p>7 Q Do you think it's possible for a mesh that's</p> <p>8 used in the vaginal space to be too stiff</p> <p>9 for use in that space?</p> <p>10 A Possible.</p> <p>11 Q How would you know when a mesh is too stiff</p> <p>12 to be safely used for stress urinary</p> <p>13 incontinence?</p> <p>14 MS. VAN STEENBURGH: Form.</p> <p>15 THE WITNESS: I think it's</p> <p>16 wrong to say it's too stiff to be safe. I</p> <p>17 think if I have a choice between a lighter</p> <p>18 mesh versus a heavier mesh for</p> <p>19 reconstruction, I would pick the lighter.</p> <p>20 But I would not say they aren't safe because</p> <p>21 of the weight. I like better the lighter</p> <p>22 weight.</p> <p>23 MR. FAES: Do you want to stop</p> <p>24 now?</p>

<p style="text-align: right;">Page 162</p> <p>1 MS. VAN STEENBURGH: Sure.</p> <p>2 MR. FAES: Okay. Let's go off</p> <p>3 the record.</p> <p>4 (Recess began - 12:07 p.m.)</p> <p>5 (Recess ended - 12:50 p.m.)</p> <p>6 BY MR. FAES:</p> <p>7 Q Okay. Doctor, we're back on the record</p> <p>8 after a short break. Are you ready to</p> <p>9 proceed?</p> <p>10 A Yes.</p> <p>11 Q Doctor, before we took a break, we were</p> <p>12 talking about the Artisyn advisory board</p> <p>13 committee that you took part in in 2012.</p> <p>14 Do you remember that?</p> <p>15 A Yes.</p> <p>16 (Exhibit No. 14 Marked.)</p> <p>17</p> <p>18 BY MR. FAES:</p> <p>19 Q I'm going to hand you a document which I</p> <p>20 have marked as Exhibit No. 14. And the top</p> <p>21 of this document states "Barriers Artisyn</p> <p>22 will need to overcome."</p> <p>23 Do you see that?</p> <p>24 A Yeah.</p>	<p style="text-align: right;">Page 164</p> <p>1 remember any specific things from the</p> <p>2 meeting.</p> <p>3 Q Do you believe that if a surgical mesh is</p> <p>4 too stiff, that that can cause an</p> <p>5 increase -- potentially cause an increase in</p> <p>6 exposures and more palpable mesh?</p> <p>7 A I don't know what mesh you're talking about.</p> <p>8 I don't know what surgeries you're talking</p> <p>9 about.</p> <p>10 Q Well, would you agree in general that if a</p> <p>11 mesh is too stiff, it can potentially cause</p> <p>12 an increase in exposures and more palpable</p> <p>13 mesh?</p> <p>14 A I can't answer that.</p> <p>15 Q You don't think it's possible for a mesh to</p> <p>16 be too stiff to where it can cause an</p> <p>17 increase in exposures and more palpable</p> <p>18 mesh?</p> <p>19 A Hernia meshes. You have all kinds of</p> <p>20 meshes. I just don't know -- I can't give</p> <p>21 you a general statement.</p> <p>22 Q Do you think it's possible for a stress</p> <p>23 urinary incontinence mesh to be too stiff to</p> <p>24 where you see an increase in exposures and</p>
<p style="text-align: right;">Page 163</p> <p>1 Q And the first item listed is "Our mesh will</p> <p>2 be too stiff. It doesn't feel as soft as</p> <p>3 current meshes on the market. They worry</p> <p>4 that they'll see an increase in exposures</p> <p>5 and more palpable mesh."</p> <p>6 Do you see that?</p> <p>7 A Yes.</p> <p>8 Q Do you remember if that was one of the</p> <p>9 feedbacks that came from you and the other</p> <p>10 physicians that were evaluating the Artisyn</p> <p>11 mesh in 2012?</p> <p>12 A No. It was a big room with many doctors</p> <p>13 with different forums. A few of them spoke</p> <p>14 a little bit. This seemed to me -- this is</p> <p>15 what we got out of the meeting.</p> <p>16 MS. VAN STEENBURGH: Listen to</p> <p>17 his question. Was this one of the things</p> <p>18 that you said?</p> <p>19 THE WITNESS: No, no. Not me.</p> <p>20 BY MR. FAES:</p> <p>21 Q So, you don't remember that being discussed</p> <p>22 at this meeting?</p> <p>23 A No. Well, yeah, they talked about soft</p> <p>24 versus not soft and this and that. I can't</p>	<p style="text-align: right;">Page 165</p> <p>1 more palpable mesh?</p> <p>2 A No. Can you make it? If you make it hard</p> <p>3 as steel, yeah. Can you make it? Probably</p> <p>4 could. Anything that I know of that is</p> <p>5 being used that is so stiff? No.</p> <p>6 Q At what point do you -- well, strike that.</p> <p>7 Is there any objective standard that</p> <p>8 you apply to determine when a mesh would be</p> <p>9 too stiff to be used for stress urinary</p> <p>10 incontinence?</p> <p>11 A I don't evaluate mesh stiffness.</p> <p>12 Q So, when you're issuing your opinions in</p> <p>13 this case regarding the TVT and TVT-O, mesh</p> <p>14 stiffness is not one of the factors that you</p> <p>15 evaluated in issuing your opinions?</p> <p>16 A No.</p> <p>17 Q Look down on number three, looks like it's</p> <p>18 got a comment from you where it states, "One</p> <p>19 of the concerns from Dr. Mjanger is that all</p> <p>20 of these Y meshes come laser cut which is</p> <p>21 great."</p> <p>22 A Where is this?</p> <p>23 Q It's number three.</p> <p>24 A Number five?</p>

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<p>1 Q Number three. I'm starting on the first 2 sentence -- the second sentence in. So, 3 I'll start over. 4 "One of the concerns from Dr. Mjanger 5 is that all these Y meshes come laser cut, 6 which is great. But when you trim the mesh, 7 the edges are prickly. He feels the prickly 8 edges can cause irritation to the bladder 9 which will cause urge incontinence." 10 Do you see that? 11 A Yes. What I was not aware of at first is 12 that stiff mesh was made extra stiff on 13 purpose by adding in Prolene. It was some 14 dissolvable component. It was made stiff on 15 purpose. That's what that discussion was 16 about. 17 Q But my first question is: Is this feedback 18 that you gave during your evaluation of the 19 Artisyn mesh? 20 A Yeah. I thought it was too stiff. I didn't 21 like the stiffness. 22 Q But you also stated that -- strike that. 23 You also stated the fact that the 24 mesh came laser cut, which was great.</p>	<p>1 incontinence and you're told, before using 2 that mesh, that the mesh is laser cut, do 3 you think that that's great? 4 A I can only compare the two that I'm using 5 which, in the old days, the nonlaser cut. 6 In the new days, the laser cut. I think the 7 laser cut is a little more forgiving when I 8 handle it. I don't see any difference in 9 the results. I don't think one is more 10 dangerous for the patient. The new one is a 11 little more stronger when it comes to 12 handling it. 13 Q And it also states that when you trim the 14 mesh, the edges are prickly and that you 15 felt that prickly edges can cause irritation 16 to the bladder which will cause urge 17 incontinence. 18 A That's strictly to sacrocolpopexy. 19 Q So, you don't think that a mesh for stress 20 urinary incontinence can have prickly edges 21 which can cause irritation to the bladder? 22 A I don't think we trim that at all and 23 there's no sewing into it, so there's no 24 bending up of the edges. It's a whole</p>
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<p>1 Is that feedback that you gave, that 2 having a laser-cut mesh was great? 3 A I can't recall that. Today, I don't even 4 know how it's cut. I can't recall that part 5 of the discussion. I can just recall that 6 there were -- when I complained of it being 7 stiff, they told me that was just -- it 8 would soften up after a few weeks. 9 Q Well, in your practice today, if someone 10 tells you that a mesh that you're going to 11 use for stress urinary incontinence is laser 12 cut, do you think that that's great? 13 MS. VAN STEENBURGH: Object to 14 form. 15 THE WITNESS: I don't think 16 it's relevant today in a prolapse surgery. I 17 use the same over and over again. 18 MS. VAN STEENBURGH: No, no. 19 He said stress urinary incontinence. 20 BY MR. FAES: 21 Q Okay. Let me re-ask the question. 22 A Yeah. 23 Q If you're evaluating a potential surgical 24 mesh for the treatment of stress urinary</p>	<p>1 different phenomenon for a sacrocolpopexy. 2 Q In theory, if a mesh for stress urinary 3 incontinence did have prickly edges, that 4 could cause irritation to the bladder, just 5 like the sacrocolpopexy mesh; right? 6 A Theoretically, if you were on a planet where 7 they sew the slings, yes -- 8 MS. VAN STEENBURGH: Object to 9 form. 10 THE WITNESS: -- but in reality 11 on planet Earth where we don't sew it, I 12 don't think it's relevant. 13 BY MR. FAES: 14 Q And have you ever seen any reports of 15 complaints to physicians -- from physicians 16 to Ethicon and Johnson & Johnson complaining 17 of TVT and TVT-O meshes having prickly 18 edges? 19 A I can't recall that. You would have to show 20 me that report. I can't recall that. 21 Q So, if there are, in fact, multiple reports 22 by physicians to Ethicon and Johnson & 23 Johnson of physicians experiencing prickly 24 edges with the TVT and the TVT-O devices,</p>

<p style="text-align: right;">Page 170</p> <p>1 does that change your opinion at all of</p> <p>2 whether or not those prickly edges can cause</p> <p>3 irritation to the bladder which can cause</p> <p>4 urge incontinence?</p> <p>5 MS. VAN STEENBURGH: Object to</p> <p>6 form.</p> <p>7 THE WITNESS: Number one, I</p> <p>8 would have to see a report before I say what</p> <p>9 I think about it. Second of all, in my</p> <p>10 practice, I can't say that I noticed anything</p> <p>11 different with the two different cuts, other</p> <p>12 than ease of handling. One I have to be a</p> <p>13 little more delicate with.</p> <p>14 BY MR. FAES:</p> <p>15 Q So, as you sit here today, in forming your</p> <p>16 opinions in this case, do you recall whether</p> <p>17 or not you've seen reports by physicians to</p> <p>18 Ethicon and Johnson & Johnson reporting</p> <p>19 prickly edges of the TVT and TVT-O devices?</p> <p>20 A I can't recall that, no. No.</p> <p>21 Q Do you recall whether or not you've seen in</p> <p>22 any documents indicating that frayed edges</p> <p>23 of the mesh was actually the number one</p> <p>24 complaint to Ethicon and Johnson & Johnson</p>	<p style="text-align: right;">Page 172</p> <p>1 fraying is actually inherent in the</p> <p>2 construction of the TVT mechanically cut</p> <p>3 mesh?</p> <p>4 A I can't recall the document, but I know it's</p> <p>5 possible I've seen it. If I see it again, I</p> <p>6 might recognize it.</p> <p>7 Q If fraying is, in fact, inherent in the</p> <p>8 construction of the TVT and TVT-O</p> <p>9 mechanically cut mesh, would that indicate a</p> <p>10 product defect to you?</p> <p>11 A Ask that again, please.</p> <p>12 Q If fraying is actually inherent in the</p> <p>13 construction of the TVT and TVT-O mesh,</p> <p>14 would that indicate to you a potential</p> <p>15 product defect in the TVT and TVT-O?</p> <p>16 MS. VAN STEENBURGH: Object to</p> <p>17 form.</p> <p>18 THE WITNESS: No. One was an</p> <p>19 older version and one is a newer version.</p> <p>20 Just because you get a new car in 2017</p> <p>21 doesn't mean the 2016 was defective. There's</p> <p>22 a new development.</p> <p>23 I've heard talk about fraying and all</p> <p>24 that stuff. I think there was an advantage</p>
<p style="text-align: right;">Page 171</p> <p>1 regarding the TVT and the TVT-O?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: Well, my point is</p> <p>5 that the edges don't fray themselves. The</p> <p>6 surgeon would have to tug on them to fray</p> <p>7 them. If they're put in right and no pulling</p> <p>8 on them, then there is no fraying. So, I</p> <p>9 think either sling could if you use it right.</p> <p>10 BY MR. FAES:</p> <p>11 Q If it turns out that mesh in the TVT and the</p> <p>12 TVT-O can, in fact, become frayed without</p> <p>13 any excessive tension or misuse by the</p> <p>14 physician, would that change any of your</p> <p>15 opinions in this case as to whether or not</p> <p>16 the TVT and TVT-O is safe and effective?</p> <p>17 MS. VAN STEENBURGH: Object to</p> <p>18 form.</p> <p>19 THE WITNESS: That's a</p> <p>20 hypothetical, because I haven't seen that. I</p> <p>21 can't speak to it if I haven't seen it.</p> <p>22 BY MR. FAES:</p> <p>23 Q So, have you seen any memorandums from</p> <p>24 Ethicon's medical directors stating that</p>	<p style="text-align: right;">Page 173</p> <p>1 with the laser cut in the fact that it is a</p> <p>2 little bit more tolerant to manhandling. We</p> <p>3 have to handle this. I mean, we have to</p> <p>4 adjust them. It's nice to have a product</p> <p>5 that tolerates a little bit more. The other</p> <p>6 one, I've never seen it be a problem for me</p> <p>7 with my patients. I know I had to take one</p> <p>8 out and put another one in. I put too much</p> <p>9 tension on it. I see less of that with the</p> <p>10 new product. I don't think one is more</p> <p>11 unsafe or safer than the other.</p> <p>12 BY MR. FAES:</p> <p>13 Q So --</p> <p>14 A I know there's been discussion that I'm</p> <p>15 aware of. In reality, I don't think it</p> <p>16 makes a heck of a lot of difference if you</p> <p>17 handle it carefully.</p> <p>18 Q If a medical device company makes two</p> <p>19 devices to treat the same condition and one</p> <p>20 is shown to be -- conclusively shown to be</p> <p>21 safer than the other, do you think the</p> <p>22 medical device company has an obligation to</p> <p>23 stop selling the less safe device?</p> <p>24 MS. VAN STEENBURGH: Object to</p>

<p style="text-align: right;">Page 174</p> <p>1 form.</p> <p>2 THE WITNESS: Well, of course.</p> <p>3 But it has also to do with the benefits. You</p> <p>4 have to weigh benefits against risk. So,</p> <p>5 there's a whole evaluation.</p> <p>6 BY MR. FAES:</p> <p>7 Q If it's shown that there's two medical</p> <p>8 devices for the same indication and they</p> <p>9 have the same benefits but one is shown to</p> <p>10 be safer than the other, do you think the</p> <p>11 medical device company has an obligation to</p> <p>12 tell doctors and patients the fact that one</p> <p>13 device is safer than the other?</p> <p>14 MS. VAN STEENBURGH: Object to</p> <p>15 form.</p> <p>16 THE WITNESS: If it's safer,</p> <p>17 yeah.</p> <p>18 BY MR. FAES:</p> <p>19 Q So, regardless of how it occurs, whether</p> <p>20 it's from the physician or it's inherent in</p> <p>21 the construction, would you agree that if</p> <p>22 the TVT mesh or the TVT-O mesh has prickly</p> <p>23 edges, that those prickly edges can</p> <p>24 potentially cause irritation to the bladder</p>	<p style="text-align: right;">Page 176</p> <p>1 Q So, in any case where you've seen where the</p> <p>2 TVT erodes into the bladder, you believe</p> <p>3 that that physician has done the procedure</p> <p>4 incorrectly; is that correct?</p> <p>5 MS. VAN STEENBURGH: Object to</p> <p>6 form.</p> <p>7 THE WITNESS: Yes, I do believe</p> <p>8 that.</p> <p>9 BY MR. FAES:</p> <p>10 Q If a physician performs the TVT retropubic</p> <p>11 procedure incorrectly to where the mesh</p> <p>12 erodes through the bladder, would you say</p> <p>13 that that physician has fallen below the</p> <p>14 standard of care in the treatment of that</p> <p>15 patient?</p> <p>16 A That's not a fair general statement. You</p> <p>17 would have to look at what -- are you</p> <p>18 dealing with a 400-pound patient or are you</p> <p>19 dealing with a normal-size patient? There</p> <p>20 are things that make the procedure</p> <p>21 difficult.</p> <p>22 Q So, if it's a normal-size patient and that</p> <p>23 occurs, do you feel that that physician has</p> <p>24 fallen below the standard of care?</p>
<p style="text-align: right;">Page 175</p> <p>1 which will cause urge incontinence?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: Are you talking</p> <p>5 about slings?</p> <p>6 BY MR. FAES:</p> <p>7 Q Yes.</p> <p>8 A They're not even around the bladder.</p> <p>9 They're around the urethra. They're far</p> <p>10 away from the bladder.</p> <p>11 Q Well, it's possible for a midurethral sling</p> <p>12 to actually erode into the bladder, isn't</p> <p>13 it?</p> <p>14 A If the surgeon put it in the wrong place.</p> <p>15 Q So, it's your testimony that the only way</p> <p>16 that a TVT mesh can become eroded into the</p> <p>17 bladder is if the surgeon placed it</p> <p>18 incorrectly?</p> <p>19 A Yes.</p> <p>20 Q So, you don't believe that a surgeon can</p> <p>21 place a TVT retropubic sling correctly and</p> <p>22 that the TVT mesh can migrate on its own and</p> <p>23 erode through the bladder?</p> <p>24 A No.</p>	<p style="text-align: right;">Page 177</p> <p>1 MS. VAN STEENBURGH: Object to</p> <p>2 form.</p> <p>3 THE WITNESS: If everything is</p> <p>4 normal, slings could not go in the bladder,</p> <p>5 no. We do look in the bladder. So, we check</p> <p>6 on it.</p> <p>7 BY MR. FAES:</p> <p>8 Q Right, during the procedure.</p> <p>9 A Right.</p> <p>10 Q But have you had instances where a physician</p> <p>11 has implanted the TVT, done the cystoscopy</p> <p>12 to look for eroded mesh in the bladder, the</p> <p>13 cystoscopy is clean, and later the TVT mesh</p> <p>14 has eroded into the bladder?</p> <p>15 MS. VAN STEENBURGH: Object to</p> <p>16 form.</p> <p>17 THE WITNESS: No.</p> <p>18 BY MR. FAES:</p> <p>19 Q It's never happened?</p> <p>20 A I don't believe that that migrates on its</p> <p>21 own. I've never seen it.</p> <p>22 Q So, I take it -- okay. So, you've never</p> <p>23 seen it. Have you ever reviewed any reports</p> <p>24 in the medical literature where that's</p>

<p style="text-align: right;">Page 178</p> <p>1 occurred?</p> <p>2 MS. VAN STEENBURGH: Evidence</p> <p>3 of migration?</p> <p>4 THE WITNESS: I don't believe</p> <p>5 slings migrate at all. They don't migrate.</p> <p>6 If you came in the OR, I would show you.</p> <p>7 They don't migrate. They sit where you put</p> <p>8 them.</p> <p>9 BY MR. FAES:</p> <p>10 Q Do you know whether that's one of the</p> <p>11 potential adverse events warned of in the</p> <p>12 TVT IFU?</p> <p>13 A Say that again.</p> <p>14 Q Do you know whether or not that's one of the</p> <p>15 potential adverse events Ethicon warns of in</p> <p>16 the TVT IFU, instructions for use?</p> <p>17 A I don't believe a sling migrates any more</p> <p>18 than an earring can migrate from one ear to</p> <p>19 another. It stays where you pierce it in.</p> <p>20 Q So, I take it then -- strike that.</p> <p>21 Have you ever reviewed the IFU, or</p> <p>22 instructions for use, for any polypropylene</p> <p>23 midurethral sling and seen a warning that</p> <p>24 the sling can migrate as one of the</p>	<p style="text-align: right;">Page 180</p> <p>1 BY MR. FAES:</p> <p>2 Q So, you'd agree that if a manufacturer warns</p> <p>3 of potential for migration of the mesh or</p> <p>4 the device in their instructions for use,</p> <p>5 that you're not even sure what that means;</p> <p>6 correct?</p> <p>7 A If I stuck it in the wrong place, it would</p> <p>8 be nice if I could say it migrated there. I</p> <p>9 think I'm responsible for where I stick it.</p> <p>10 If you find it where it should be, it's most</p> <p>11 likely I put it there.</p> <p>12 Q I understand, but my question is a little</p> <p>13 different than that.</p> <p>14 My question is: If a medical device</p> <p>15 manufacturer warned of mesh or device</p> <p>16 migration as a potential adverse event of</p> <p>17 that device, are you saying that you don't</p> <p>18 even know what that means if they put that</p> <p>19 warning in there?</p> <p>20 MS. VAN STEENBURGH: Object to</p> <p>21 form.</p> <p>22 THE WITNESS: I don't believe</p> <p>23 it migrates. I would like to know -- I</p> <p>24 just -- I don't think it migrates, meaning</p>
<p style="text-align: right;">Page 179</p> <p>1 potential adverse reactions?</p> <p>2 A I have read the document. I don't believe</p> <p>3 this thing migrates.</p> <p>4 Q So, any manufacturer who puts that as a</p> <p>5 potential adverse reaction in their IFU, you</p> <p>6 believe that that company is putting</p> <p>7 incorrect information in their IFU?</p> <p>8 MS. VAN STEENBURGH: Object to</p> <p>9 form.</p> <p>10 THE WITNESS: I don't know what</p> <p>11 they put in the meaning of "migrate." I just</p> <p>12 don't know what they're talking about there.</p> <p>13 Because the way I see it, things -- if you</p> <p>14 pierce something in, it usually sits where</p> <p>15 you pierce it. The thing is the piercing</p> <p>16 goes in. I've never seen them migrate. I</p> <p>17 don't believe they migrate. Can it slide in</p> <p>18 the hole? Possibly. Does it migrate? No, I</p> <p>19 don't believe that.</p> <p>20 So, I'm sure there's some language</p> <p>21 misunderstanding here or something. We're</p> <p>22 talking about two different things. I don't</p> <p>23 believe they migrate in that form there.</p> <p>24</p>	<p style="text-align: right;">Page 181</p> <p>1 moving from one point to another.</p> <p>2 BY MR. FAES:</p> <p>3 Q So, Doctor, we've talked a little bit about</p> <p>4 the fact that you are basing your opinions</p> <p>5 regarding differences between the</p> <p>6 mechanically cut mesh and laser-cut mesh for</p> <p>7 the TVT and TVT-O on your clinical</p> <p>8 experience, is that accurate, that you're</p> <p>9 basing your opinions on part of your</p> <p>10 clinical experience?</p> <p>11 A Clinical experience and also my education,</p> <p>12 my going to review courses and meetings,</p> <p>13 seminars every year, reading texts,</p> <p>14 reviewing articles. The whole body of</p> <p>15 learning.</p> <p>16 Q So, let me ask you this: Do you keep track</p> <p>17 of how many mechanically cut slings you've</p> <p>18 placed versus laser-cut slings that you've</p> <p>19 placed?</p> <p>20 A No.</p> <p>21 Q So, you've never tracked whether -- so, I</p> <p>22 take it since you can't even -- strike that.</p> <p>23 I take it since you haven't even</p> <p>24 tracked how many laser-cut slings you've put</p>

<p style="text-align: right;">Page 182</p> <p>1 in versus mechanically cut slings, you've</p> <p>2 never tracked whether that difference</p> <p>3 impacts your complication rates; correct?</p> <p>4 A No, I never noticed any difference at all</p> <p>5 once the sling is put in correctly.</p> <p>6 Q But my question is: You've never done any</p> <p>7 kind of formal analysis of your own clinical</p> <p>8 practice regarding difference in</p> <p>9 complication rates between the mechanically</p> <p>10 cut mesh and the laser-cut mesh; correct?</p> <p>11 A Correct.</p> <p>12 Q A couple of the articles that you discuss in</p> <p>13 your expert reports are from Dr. Ulmsten's</p> <p>14 original cohort of patients in 1996;</p> <p>15 correct?</p> <p>16 A Correct.</p> <p>17 Q Are you aware that Dr. Nilsson was actually</p> <p>18 paid by Ethicon and Johnson & Johnson for</p> <p>19 the results of that study?</p> <p>20 A No.</p> <p>21 Q So, you haven't seen any documents or</p> <p>22 testimony indicating that Ethicon and</p> <p>23 Johnson & Johnson actually paid Dr. Ulmsten</p> <p>24 \$450,000 to publish the results of that</p>	<p style="text-align: right;">Page 184</p> <p>1 incontinence. We have today a large amount</p> <p>2 of data about these. What the original</p> <p>3 inventors dealt with and how they came about</p> <p>4 their findings, I just don't know anything</p> <p>5 about it. I think at this point today, it's</p> <p>6 irrelevant. It's taken on a life of its own</p> <p>7 and it's been used around the world for so</p> <p>8 long.</p> <p>9 Q But you'd agree that the Ulmsten/Nilsson</p> <p>10 series of studies is actually the longest</p> <p>11 follow-up for the TVT at this point in time;</p> <p>12 right?</p> <p>13 A Yes.</p> <p>14 Q In fact, it's the longest follow-up of any</p> <p>15 polypropylene midurethral sling on the</p> <p>16 market; right?</p> <p>17 A It would have to be. They invented it.</p> <p>18 They are the first to publish on it. Their</p> <p>19 information is the oldest.</p> <p>20 Q And you don't think the fact that Ethicon</p> <p>21 and Johnson & Johnson paid for the</p> <p>22 clinical -- strike that.</p> <p>23 You don't think the fact that Ethicon</p> <p>24 and Johnson & Johnson paid Dr. Ulmsten to</p>
<p style="text-align: right;">Page 183</p> <p>1 study but would only pay that amount if the</p> <p>2 results were similar to his 1996 study?</p> <p>3 MS. VAN STEENBURGH: Object to</p> <p>4 form.</p> <p>5 THE WITNESS: No.</p> <p>6 BY MR. FAES:</p> <p>7 Q Do you think such an incentive payment would</p> <p>8 inject potential bias into the reporting of</p> <p>9 those results if the doctor is told "We'll</p> <p>10 pay you to publish this article but only if</p> <p>11 the results are as good as your previous</p> <p>12 paper"?</p> <p>13 MS. VAN STEENBURGH: Object to</p> <p>14 form.</p> <p>15 THE WITNESS: That went on in</p> <p>16 the last century. I have no opinion about</p> <p>17 what they did back then.</p> <p>18 BY MR. FAES:</p> <p>19 Q But those original patients are the same</p> <p>20 patients that were followed up for 17 years</p> <p>21 in Nilsson's follow-up study; right?</p> <p>22 A I think that results -- there's been so many</p> <p>23 studies on these things, so many, probably</p> <p>24 more than on anything else ever used for</p>	<p style="text-align: right;">Page 185</p> <p>1 publish the original results of that</p> <p>2 clinical study in any way effects or injects</p> <p>3 potential bias into those results?</p> <p>4 MS. VAN STEENBURGH: Object to</p> <p>5 form.</p> <p>6 THE WITNESS: I can't speak to</p> <p>7 it. I don't know enough about it. There are</p> <p>8 probably many sides to that. I have no clue</p> <p>9 about that.</p> <p>10 MR. FAES: Kind of off track</p> <p>11 there. I'm going to go back to the Artisyn</p> <p>12 lab that you participated in.</p> <p>13 (Exhibit No. 15 Marked.)</p> <p>14</p> <p>15 BY MR. FAES:</p> <p>16 Q I'm going to hand you, Doctor, what's been</p> <p>17 marked as Exhibit No. 15 to your deposition.</p> <p>18 And this is a PowerPoint entitled "Artisyn</p> <p>19 Y-Shaped Mesh Advisory Board, March 11,</p> <p>20 2012."</p> <p>21 Do you see that?</p> <p>22 A Uh-huh.</p> <p>23 Q And if you turn to the inside page, it lists</p> <p>24 a number of doctors that are faculty, and</p>

<p style="text-align: right;">Page 186</p> <p>1 you're listed there on the bottom, Ron</p> <p>2 Mjanger; right?</p> <p>3 A Yeah.</p> <p>4 Q So, you were faculty for this event?</p> <p>5 A I was one of the guys that told them what I</p> <p>6 thought about it. There was no teaching or</p> <p>7 anything. Just seeing it and feeling it for</p> <p>8 the first time and sewing it into a cadaver</p> <p>9 and answering questions about what it felt</p> <p>10 like.</p> <p>11 Q And if you look at the next page, there's</p> <p>12 also a number of Ethicon Gynecare attendees</p> <p>13 listed?</p> <p>14 A Uh-huh.</p> <p>15 Q Do you know who any of these individuals</p> <p>16 are, as you sit here today?</p> <p>17 A One of them.</p> <p>18 Q Who is that?</p> <p>19 A Aaron Kirkemo.</p> <p>20 Q And is that because Dr. Kirkemo actually</p> <p>21 used to practice in the Minnesota area?</p> <p>22 A Uh-huh. Yes.</p> <p>23 Q Have you -- when's the last time you've</p> <p>24 spoken to Dr. Kirkemo?</p>	<p style="text-align: right;">Page 188</p> <p>1 Artisyn Y mesh?</p> <p>2 A First time I've seen it. I don't know.</p> <p>3 Q So, you don't remember that being discussed</p> <p>4 at any --</p> <p>5 A No.</p> <p>6 Q -- of the Artisyn ad boards that you</p> <p>7 attended?</p> <p>8 A No.</p> <p>9 Q If you look at the bottom left corner in</p> <p>10 here, it states, "Less</p> <p>11 contracture/shrinkage."</p> <p>12 Do you see that?</p> <p>13 A Yep.</p> <p>14 Q Do you recall -- well, strike that.</p> <p>15 Was that one of the things that was</p> <p>16 discussed at the Artisyn Y mesh meeting,</p> <p>17 that the +M material in the Artisyn mesh</p> <p>18 shrank less or would have less contracture</p> <p>19 than other meshes that were currently</p> <p>20 available?</p> <p>21 MS. VAN STEENBURGH: Object to</p> <p>22 form.</p> <p>23 THE WITNESS: I can't remember</p> <p>24 that. What year is this?</p>
<p style="text-align: right;">Page 187</p> <p>1 A Some years ago I ran across him at a meeting</p> <p>2 where he was working for a company -- I</p> <p>3 don't know which company. I don't know what</p> <p>4 he was there for. But he was not there as a</p> <p>5 doctor. He was there as a corporate person.</p> <p>6 He's quit surgery. He's retired from that.</p> <p>7 Q But at this time, in 2012, he was an</p> <p>8 associate medical director with Ethicon and</p> <p>9 Johnson & Johnson; right?</p> <p>10 MS. VAN STEENBURGH: Object to</p> <p>11 form.</p> <p>12 THE WITNESS: I don't know. I</p> <p>13 don't know what he was.</p> <p>14 BY MR. FAES:</p> <p>15 Q If you turn to I think it's page 2 of this</p> <p>16 document, pages ending in '2717 --</p> <p>17 A Okay.</p> <p>18 Q -- and if you see in the section here, it</p> <p>19 talks about the unique +M material having</p> <p>20 better handling and better tissue in-growth.</p> <p>21 Do you see that?</p> <p>22 A Yes.</p> <p>23 Q Did you understand that to be referring to</p> <p>24 the +M mesh material that was used in the</p>	<p style="text-align: right;">Page 189</p> <p>1 BY MR. FAES:</p> <p>2 Q This is dated March 11, 2012, if you look on</p> <p>3 the front cover.</p> <p>4 A I don't remember this.</p> <p>5 Q Do you have an understanding of whether or</p> <p>6 not a lighter-weight, larger-core mesh like</p> <p>7 the +M material that's used in the Artisyn</p> <p>8 is less susceptible to mesh contracture and</p> <p>9 shrinkage than heavier-weight meshes?</p> <p>10 MS. VAN STEENBURGH: Object to</p> <p>11 form.</p> <p>12 THE WITNESS: I don't know. I</p> <p>13 don't use it, so I don't have experience with</p> <p>14 that.</p> <p>15 BY MR. FAES:</p> <p>16 Q So, you wouldn't have -- strike that.</p> <p>17 You would agree that you wouldn't</p> <p>18 have any opinion then if this Ultrapro or +M</p> <p>19 material were used in a sling for stress</p> <p>20 urinary incontinence as to whether or not</p> <p>21 that would result in less contracture or</p> <p>22 shrinkage than a TVT sling?</p> <p>23 A No, no opinion on that.</p> <p>24 Q Have you ever reviewed any peer-reviewed</p>

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<p>1 medical journals that discuss the use of</p> <p>2 Ultrapro mesh used in a sling for stress</p> <p>3 urinary incontinence and what those clinical</p> <p>4 results were?</p> <p>5 A I can't recall it.</p> <p>6 Q It also states, over on the other page, that</p> <p>7 the +M mesh and the Artisyn mesh results in</p> <p>8 less foreign material being left behind.</p> <p>9 Do you remember that being discussed</p> <p>10 as a potential clinical benefit in any of</p> <p>11 your Artisyn board meetings?</p> <p>12 A Artisyn board meetings?</p> <p>13 MS. VAN STEENBURGH: This</p> <p>14 particular one.</p> <p>15 BY MR. FAES:</p> <p>16 Q This is discussing the --</p> <p>17 A I only went to one thing. Like I said, we</p> <p>18 sewed in mesh in a cadaver and answered some</p> <p>19 questions. I don't remember any of these</p> <p>20 details.</p> <p>21 Q Okay. Do you remember being told that the</p> <p>22 +M mesh in the Artisyn device had the</p> <p>23 potential to reduce dyspareunia, or painful</p> <p>24 sexual intercourse?</p>	<p>1 about the Artisyn mesh. I never used it.</p> <p>2 BY MR. FAES:</p> <p>3 Q So, you'd agree that you wouldn't -- I</p> <p>4 wouldn't expect you to offer any opinions in</p> <p>5 this case as to whether or not the use of</p> <p>6 this +M mesh or Ultrapro mesh would prevent</p> <p>7 shortening of the vagina and pain associated</p> <p>8 with the mesh?</p> <p>9 A I have -- like I said, I have not used it,</p> <p>10 don't know much about it, never showed any</p> <p>11 interest in it.</p> <p>12 Q I'm just about finished with this document,</p> <p>13 but if you can turn to page 15 of this.</p> <p>14 A (Complying.)</p> <p>15 Q If you look at the second bullet point on</p> <p>16 this, it asks, "Defining the Value</p> <p>17 Proposition of Artisyn." It asks, "What</p> <p>18 should we say about Artisyn to convert a</p> <p>19 Y-Mesh user?"</p> <p>20 Do you see that?</p> <p>21 A Why would I say anything about it --</p> <p>22 MS. VAN STEENBURGH: No, no,</p> <p>23 no. First, he's asking whether you see this.</p> <p>24 THE WITNESS: I see it, yes.</p>
Page 191	Page 193
<p>1 A No, no.</p> <p>2 Q Do you have any understanding of whether or</p> <p>3 not a lighter-weight, larger-core mesh,</p> <p>4 likely the Ultrapro or the Artisyn mesh, has</p> <p>5 the potential to reduce dyspareunia in a</p> <p>6 patient?</p> <p>7 A I don't know.</p> <p>8 Q It also states that one of the -- strike</p> <p>9 that.</p> <p>10 If you look down in the bottom</p> <p>11 right-hand corner, it also states that the</p> <p>12 Artisyn Y-Shaped mesh material prevents</p> <p>13 shortening of the vagina and pain</p> <p>14 associated.</p> <p>15 Do you see that?</p> <p>16 A I don't remember that.</p> <p>17 Q Do you have an understanding of whether or</p> <p>18 not the Artisyn Y mesh or the Ultrapro mesh</p> <p>19 would reduce shortening of the vagina and</p> <p>20 pain associated when used instead of a mesh</p> <p>21 like the TVT?</p> <p>22 MS. VAN STEENBURGH: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: I don't know much</p>	<p>1 BY MR. FAES:</p> <p>2 Q Were you ever asked, during any of your</p> <p>3 Artisyn board meetings, for any assistance</p> <p>4 in what Ethicon or people who work for</p> <p>5 Ethicon should say to convert an existing</p> <p>6 Y-Mesh user, like yourself, because you were</p> <p>7 using the Restorelle at that time; right?</p> <p>8 A First of all, I was never to any Artisyn</p> <p>9 board meetings. I went to one cadaver lab.</p> <p>10 Q Okay.</p> <p>11 A I can't recall and I was not trying to</p> <p>12 convince anyone to use it. I don't use it</p> <p>13 myself.</p> <p>14 Q Okay.</p> <p>15 A I sewed it in a cadaver and said what I felt</p> <p>16 in my hand.</p> <p>17 (Exhibit No. 16 Marked.)</p> <p>18</p> <p>19 BY MR. FAES:</p> <p>20 Q Doctor, I'm going to hand you what's been</p> <p>21 marked as Exhibit No. 16 to your deposition.</p> <p>22 This is an e-mail. At the top, it's dated</p> <p>23 March 23rd of 2012. Actually, what I want</p> <p>24 to ask you about is the e-mail that starts</p>

<p style="text-align: right;">Page 194</p> <p>1 on May 22nd, 2012, at 4:16, at about the</p> <p>2 middle of the page, from your sales rep,</p> <p>3 Laura Mettner.</p> <p>4 Do you see that?</p> <p>5 A Say that again.</p> <p>6 Q What I want to ask you about on this</p> <p>7 document is this e-mail from your sales rep,</p> <p>8 Laura Mettner, on May 22nd of 2012.</p> <p>9 A Okay. Right.</p> <p>10 Q "Dr. Mjanger, who attended the advisory</p> <p>11 board in March, posed a question to me that</p> <p>12 I thought was interesting and we should use</p> <p>13 to our advantage." And it states, "When</p> <p>14 doing studies on Y Mesh strength, he said it</p> <p>15 would be important to test the strength at</p> <p>16 different widths because no surgeon is</p> <p>17 placing the mesh without trimming it and it</p> <p>18 wouldn't be a fair strength test not to trim</p> <p>19 it first."</p> <p>20 Do you see that?</p> <p>21 A Yes.</p> <p>22 Q Was that feedback that you gave to Ethicon</p> <p>23 and Johnson & Johnson following the Artisyn</p> <p>24 advisory board that you attended in March?</p>	<p style="text-align: right;">Page 196</p> <p>1 came to market. The rep was in St. Paul and</p> <p>2 asked me to use it. I never switched to use</p> <p>3 it. I had a few comments to her when she</p> <p>4 approached me to tell me I should switch. I</p> <p>5 had no reason to leave what I was using. It</p> <p>6 might be as good as what I had. I didn't see</p> <p>7 it as better.</p> <p>8 BY MR. FAES:</p> <p>9 Q You'd agree then that it's important for a</p> <p>10 medical device company to do testing of a</p> <p>11 mesh before that mesh is released into the</p> <p>12 marketplace; right?</p> <p>13 A Yeah.</p> <p>14 Q And, in fact, even with regard to the TVT,</p> <p>15 do you believe it would be important for</p> <p>16 Ethicon to test and know what different</p> <p>17 forces can be expected to be applied to that</p> <p>18 mesh during placement before it's released</p> <p>19 to the market?</p> <p>20 MS. VAN STEENBURGH: Object to</p> <p>21 form.</p> <p>22 THE WITNESS: I don't think it</p> <p>23 mixes at all. My comment to her about this</p> <p>24 mesh -- this mesh was meant to be trimmed.</p>
<p style="text-align: right;">Page 195</p> <p>1 A Yes. This look like something I probably</p> <p>2 said to the sales rep when she approached</p> <p>3 me. She usually came in the operating room</p> <p>4 area and tried to sell me things while I was</p> <p>5 scrubbing my hands. As far as I remember --</p> <p>6 I don't remember saying this, but I know</p> <p>7 what it's alluding to. The mesh was a</p> <p>8 pretty good size and you can trim it to any</p> <p>9 size you want. They talked about the</p> <p>10 strength of this. I probably made a comment</p> <p>11 saying that, you know, saying we can trim</p> <p>12 it. Maybe you should have more than one</p> <p>13 size and not just one big piece and you can</p> <p>14 trim it to this. So, that's probably a</p> <p>15 comment I made to her along the way</p> <p>16 somewhere.</p> <p>17 Q So, this was a comment that you made that</p> <p>18 you thought more testing needed to be done</p> <p>19 on this particular mesh before it was</p> <p>20 reached to the market for general use;</p> <p>21 right?</p> <p>22 MS. VAN STEENBURGH: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: Well, the mesh</p>	<p style="text-align: right;">Page 197</p> <p>1 The TVT slings are not meant to be trimmed.</p> <p>2 You don't trim them. They are what they are.</p> <p>3 This was a trimmable mesh, so we can cut them</p> <p>4 to any size. So, my comment was -- I was</p> <p>5 trying to come up with reasons why not to use</p> <p>6 it. I wasn't interested in using it.</p> <p>7 BY MR. FAES:</p> <p>8 Q But you know at least the mechanically cut</p> <p>9 mesh with the TVT, while it's not trimmed by</p> <p>10 the physician, it is trimmed or cut before</p> <p>11 it's sold; right?</p> <p>12 A Yeah.</p> <p>13 Q By something mechanical.</p> <p>14 A Yeah.</p> <p>15 Q Do you know how it's cut?</p> <p>16 A Pardon me?</p> <p>17 Q Do you know how it's cut?</p> <p>18 A Not really.</p> <p>19 Q Okay. So, you don't know, for instance, on</p> <p>20 essentially a guillotine machine?</p> <p>21 A I don't know how they cut it. I just know</p> <p>22 the product when I get it in my hand.</p> <p>23 Q So, being the -- knowing that the TVT mesh</p> <p>24 is actually -- or at least the TVT</p>

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<p>1 mechanically cut mesh is actually cut not by</p> <p>2 the physician but by the company prior to</p> <p>3 the physician using it, you think it would</p> <p>4 be important for the company to test and</p> <p>5 know what different forces are applied to</p> <p>6 that mesh during implantation before they</p> <p>7 sell it to the public?</p> <p>8 MS. VAN STEENBURGH: Object to</p> <p>9 form.</p> <p>10 THE WITNESS: Yeah, but I don't</p> <p>11 see the relevance with a sling. I've never</p> <p>12 in my life seen a sling break. I've seen Y</p> <p>13 mesh break.</p> <p>14 BY MR. FAES:</p> <p>15 Q But you've seen it deform; right?</p> <p>16 A If you yank on it, pull it.</p> <p>17 Q Right. Have you seen any -- strike that.</p> <p>18 Do you intend to offer any opinions</p> <p>19 in this case as to how much the sling can</p> <p>20 become elongated during normal implantation</p> <p>21 according to the instructions for use?</p> <p>22 A No.</p> <p>23 Q So, if one of Ethicon's engineers, for</p> <p>24 example, stated that he believed that during</p>	<p>1 certainty that that number is correct or</p> <p>2 incorrect, or you just don't know one way or</p> <p>3 the other?</p> <p>4 A That 50 percent number, I have no</p> <p>5 recollection of seeing that anywhere.</p> <p>6 MS. VAN STEENBURGH: The</p> <p>7 question is: Are you going to offer an</p> <p>8 opinion as to whether that's correct or not?</p> <p>9 That's not in your report.</p> <p>10 THE WITNESS: No, I'm not going</p> <p>11 to have an opinion on that. I don't know if</p> <p>12 anybody would have an opinion on that. No.</p> <p>13 (Exhibit No. 17 Marked.)</p> <p>14</p> <p>15 BY MR. FAES:</p> <p>16 Q Doctor, I'm going to hand you what's been</p> <p>17 marked as Exhibit No. 17 to this deposition.</p> <p>18 I'll try to go over this with you real</p> <p>19 quickly.</p> <p>20 MS. VAN STEENBURGH: There</p> <p>21 isn't much to it. You have to go quick.</p> <p>22 Just kidding.</p> <p>23 MR. FAES: Right.</p> <p>24 MS. VAN STEENBURGH: A little</p>
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<p>1 normal implantation of the TVT, that the</p> <p>2 sling may elongate up to 50 percent at the</p> <p>3 maximum, you have no reason to agree or</p> <p>4 disagree with that statement; is that</p> <p>5 accurate?</p> <p>6 A I never heard that statement. It sounds far</p> <p>7 off to me.</p> <p>8 Q As you sit here today, do you intend to</p> <p>9 offer any opinions, either agreeing or</p> <p>10 disagreeing, with that statement?</p> <p>11 A What's the statement? I don't quite</p> <p>12 understand your statement.</p> <p>13 Q The statement is: During implantation of</p> <p>14 the TVT mesh, that Ethicon engineers have</p> <p>15 found that the TVT mesh can elongate up to</p> <p>16 50 percent at the maximum.</p> <p>17 MS. VAN STEENBURGH: Object to</p> <p>18 form.</p> <p>19 THE WITNESS: I just don't</p> <p>20 believe that. I've never heard that. It</p> <p>21 just doesn't make sense to me.</p> <p>22 BY MR. FAES:</p> <p>23 Q Okay. Do you intend to offer an opinion in</p> <p>24 this case to a reasonable degree of medical</p>	<p>1 levity.</p> <p>2 BY MR. FAES:</p> <p>3 Q This is an e-mail from your Ethicon sales</p> <p>4 rep, Laura Mettner, dated August 7 of 2017</p> <p>5 [sic] to a Lindsay Mason. And the subject</p> <p>6 is "Mjanger," which is you; right?</p> <p>7 A Right.</p> <p>8 THE COURT REPORTER: You just</p> <p>9 said August 7 of 2017. Is that right?</p> <p>10 MR. FAES: No. Let me start</p> <p>11 over.</p> <p>12 BY MR. FAES:</p> <p>13 Q So, this is an e-mail dated August 7, 2012,</p> <p>14 from your sales rep Laura Mettner, to a</p> <p>15 Lindsay Mason.</p> <p>16 Do you see that?</p> <p>17 A Yes.</p> <p>18 Q And the subject is you.</p> <p>19 A Yes.</p> <p>20 Q Do you know who Lindsay Mason is?</p> <p>21 A No.</p> <p>22 Q You never met any sales rep from Ethicon and</p> <p>23 Johnson & Johnson named Lindsay Mason?</p> <p>24 A I may have. I've met many of them. I have</p>

<p style="text-align: right;">Page 202</p> <p>1 no idea. I don't know the name.</p> <p>2 Q It says this is what she texted Dr. Mjanger.</p> <p>3 "Hi, Dr. Mjanger. Artisyn Y-Mesh is</p> <p>4 approved at St. John's. I will have a</p> <p>5 sterile sample (no charge) available to you</p> <p>6 to try next Friday for your 7:30 case. Have</p> <p>7 you requested Artisyn at United yet to begin</p> <p>8 the value analysis process there? I cannot</p> <p>9 bring it into United without you beginning</p> <p>10 the process with Ginger."</p> <p>11 Do you see that?</p> <p>12 MS. VAN STEENBURGH: "If you</p> <p>13 want it brought in, of course."</p> <p>14 THE WITNESS: Yeah, I remember</p> <p>15 her pestering to get me to start using this.</p> <p>16 I don't know if it ever got approved at</p> <p>17 United. I don't use it. I believe I used</p> <p>18 three of these and I think they were</p> <p>19 implanted at St. John's. I can't recall that</p> <p>20 far back. If I don't remember wrong, I did</p> <p>21 sew in three of them. They were okay. But I</p> <p>22 never switched.</p> <p>23 BY MR. FAES:</p> <p>24 Q So, that was my question. Is this what you</p>	<p style="text-align: right;">Page 204</p> <p>1 the TVT Abbrevio?</p> <p>2 A Yeah. You have to sell them some benefit</p> <p>3 with something new or different or a better</p> <p>4 price or something.</p> <p>5 Q Do you recall if anyone -- well, strike</p> <p>6 that.</p> <p>7 Did anyone at Ethicon and</p> <p>8 Johnson & Johnson ever bring you any kind of</p> <p>9 form to sign regarding the Artisyn mesh?</p> <p>10 A I can't remember. We had an unsigned form</p> <p>11 here. I'm sure there --</p> <p>12 MS. VAN STEENBURGH: You don't</p> <p>13 know.</p> <p>14 THE WITNESS: I don't know.</p> <p>15 I've never seen it or recall it. The rep</p> <p>16 probably has them in her suitcase all the</p> <p>17 time if anyone will sign them. I don't know.</p> <p>18 I can't answer it.</p> <p>19 BY MR. FAES:</p> <p>20 Q Do you see the last paragraph of this, it</p> <p>21 looks like Lindsay Mason is covering this</p> <p>22 Artisyn Y mesh case for Laura Mettner. And</p> <p>23 it states, "Thanks for covering the case.</p> <p>24 Take notes and ask him (and Tina. Do not</p>
<p style="text-align: right;">Page 203</p> <p>1 were referring to earlier, that people from</p> <p>2 Ethicon and Johnson & Johnson were kind of</p> <p>3 after you to try out this new Artisyn Y</p> <p>4 mesh?</p> <p>5 A Yes.</p> <p>6 Q And you ultimately decided not to use it</p> <p>7 regularly in your practice; right?</p> <p>8 A No. I can't say for sure, but I think I</p> <p>9 sewed in three of them. I know for sure I</p> <p>10 did one. I think it was three. And</p> <p>11 basically told them I tried it; I'm going to</p> <p>12 stay with what I use.</p> <p>13 Q It talks about "the value analysis process</p> <p>14 at United."</p> <p>15 Do you know what that refers to?</p> <p>16 A Yeah. When you're going to get in a new</p> <p>17 product, it goes through a big evaluation.</p> <p>18 You have to -- it has to do with money. The</p> <p>19 hospital will not just go out and buy</p> <p>20 something because one doctor requested it.</p> <p>21 They have to do a whole evaluation.</p> <p>22 Q Is one of the elements of that process</p> <p>23 filling out a form describing the clinical</p> <p>24 benefit of the product, like you signed for</p>	<p style="text-align: right;">Page 205</p> <p>1 forget to get her opinion) what their</p> <p>2 thoughts are on it. I know I'm putting a</p> <p>3 lot of pressure on you about this</p> <p>4 case...he's my biggest target."</p> <p>5 Do you see that?</p> <p>6 A I see this.</p> <p>7 Q Did you have an understanding at this time</p> <p>8 that you were Ethicon's biggest target to</p> <p>9 get them -- strike that.</p> <p>10 Did you have an understanding at this</p> <p>11 time that you were Ethicon's biggest target</p> <p>12 for the use of the Artisyn Y mesh?</p> <p>13 MS. VAN STEENBURGH: Object to</p> <p>14 form.</p> <p>15 THE WITNESS: Yes. I know</p> <p>16 that -- I have a large-volume practice and</p> <p>17 that's the only reason why.</p> <p>18 (Exhibit No. 18 Marked.)</p> <p>19</p> <p>20 BY MR. FAES:</p> <p>21 Q Doctor, I'm going to hand you what's been</p> <p>22 marked as Exhibit No. 18 to your deposition.</p> <p>23 And this is an e-mail dated March 2nd of</p> <p>24 2012 to you from Brian Luscombe.</p>

<p style="text-align: right;">Page 206</p> <p>1 Do you see that?</p> <p>2 A Yeah.</p> <p>3 Q And it states, "As per our discussion</p> <p>4 earlier, below are links to the assets</p> <p>5 requested. Please click on an individual</p> <p>6 link to view." And then it's got a link to</p> <p>7 the Prolift+M IFU, the TVT Abbrevio IFU, and</p> <p>8 the TVT Exact IFU.</p> <p>9 Do you see that?</p> <p>10 A Yeah, I see it.</p> <p>11 Q And it states, "Please contact me with any</p> <p>12 questions or concerns"; right?</p> <p>13 A Yes.</p> <p>14 Q What discussion did you have with Brian</p> <p>15 Luscombe in March of 2012 that prompted him</p> <p>16 to send you the IFUs for these three</p> <p>17 products?</p> <p>18 A I have no clue. These salespeople send me</p> <p>19 e-mails by the dozens; most of them I glance</p> <p>20 at them and don't read them. They call me</p> <p>21 constantly. I have no clue what this is.</p> <p>22 None. I can't recall it.</p> <p>23 Q So, you can't recall any reason why you</p> <p>24 would have had an occasion to request IFUs</p>	<p style="text-align: right;">Page 208</p> <p>1 first robot for I'll call it ASC?</p> <p>2 A 2007.</p> <p>3 Q So, was it around 2007 that you stopped</p> <p>4 using the Prolift?</p> <p>5 A Probably.</p> <p>6 Q I don't think the Prolift+M actually came</p> <p>7 out until 2009. So, if it didn't come out</p> <p>8 until 2009 --</p> <p>9 A I know there was talk about it. I can't</p> <p>10 really recall much about that.</p> <p>11 Q Okay. So, once you started using the robot</p> <p>12 for ASCs, when you use the robot, do you</p> <p>13 always implant the mesh abdominally as</p> <p>14 opposed to transvaginally?</p> <p>15 A Yes.</p> <p>16 Q Do you feel that that's a better approach to</p> <p>17 implant meshes abdominally for pelvic organ</p> <p>18 prolapse as opposed to transvaginally?</p> <p>19 MS. VAN STEENBURGH: Objection.</p> <p>20 THE WITNESS: For me, it is.</p> <p>21 BY MR. FAES:</p> <p>22 Q Why do you feel it's better?</p> <p>23 A I'm an experienced laparoscopic robotic</p> <p>24 surgeon. That's my specialty.</p>
<p style="text-align: right;">Page 207</p> <p>1 or instructions for use?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: I cannot recall.</p> <p>5 BY MR. FAES:</p> <p>6 Q So, the Prolift+M, that's a product that</p> <p>7 you've used in your practice; right?</p> <p>8 A I think it came at the end of the time. I</p> <p>9 can't really recall it. I think it came</p> <p>10 about the time I quit using it. I probably</p> <p>11 have used a few, but I quit using those a</p> <p>12 long time before Ethicon quit making them.</p> <p>13 Q Okay. So, this time, March of 2012, you</p> <p>14 probably weren't even using the Prolift or</p> <p>15 the Prolift+M?</p> <p>16 A No.</p> <p>17 Q Okay. Why did you stop using the Prolift</p> <p>18 and the Prolift+M products?</p> <p>19 MS. VAN STEENBURGH: Form.</p> <p>20 THE WITNESS: Because we got</p> <p>21 the first robot and I started just doing</p> <p>22 sacrocolpopexy.</p> <p>23 BY MR. FAES:</p> <p>24 Q So, when was it that you first got your</p>	<p style="text-align: right;">Page 209</p> <p>1 Q And what do you use, the da Vinci robot?</p> <p>2 A Yes.</p> <p>3 Q Doctor, I want to ask you about some things</p> <p>4 in your expert report which I think is</p> <p>5 Exhibit 2. You might have to go back to</p> <p>6 that to refer to it when I ask you</p> <p>7 questions.</p> <p>8 A (Complying.)</p> <p>9 Q So, if you look in the paragraph titled</p> <p>10 "Disclosure of Opinions," in about the</p> <p>11 middle of that paragraph, you state, "In</p> <p>12 summary, in my opinion, the TVT-O and TVT --</p> <p>13 strike that.</p> <p>14 It states, "In summary, in my</p> <p>15 opinion, the TVT and TVT-O designs are</p> <p>16 reasonably safe for their intended use."</p> <p>17 Do you see that?</p> <p>18 A Yes.</p> <p>19 Q And if you look at the last page of your</p> <p>20 report, you actually give a similar</p> <p>21 statement where you say, "In conclusion, the</p> <p>22 TVT and TVT-O, whether mechanically cut or</p> <p>23 laser cut, has been shown to be</p> <p>24 appropriately designed for the reasonably</p>

<p style="text-align: right;">Page 210</p> <p>1 safe and effective use for treating female</p> <p>2 stress urinary incontinence."</p> <p>3 Do you see that?</p> <p>4 A Yes.</p> <p>5 Q Are those opinions that you intend to offer</p> <p>6 in this case?</p> <p>7 A Yes.</p> <p>8 Q So, is there some particular reason why in</p> <p>9 both of these opinions you've used the</p> <p>10 qualifier "reasonably"?</p> <p>11 A Because they are reasonably safe.</p> <p>12 Q Is it your opinion that the designs are safe</p> <p>13 or that they're reasonably safe?</p> <p>14 MS. VAN STEENBURGH: Object to</p> <p>15 form.</p> <p>16 THE WITNESS: They're the</p> <p>17 safest we have, the best we have this year.</p> <p>18 What we have next year, I don't know. But</p> <p>19 they are reasonably safe.</p> <p>20 BY MR. FAES:</p> <p>21 Q So, when you're giving your opinion that</p> <p>22 they're reasonably safe, you're saying</p> <p>23 they're reasonably safe in comparison to</p> <p>24 other available treatment options; right?</p>	<p style="text-align: right;">Page 212</p> <p>1 more effective, safer, or has been studied</p> <p>2 as much or as long as the TVT or the TVT-O?</p> <p>3 A Yes.</p> <p>4 Q But you'd agree that you haven't engaged in</p> <p>5 the study of whether or not, for example,</p> <p>6 the TVT Abbrevio is a safer alternative</p> <p>7 design to the TVT-O?</p> <p>8 A That's correct.</p> <p>9 Q And you haven't engaged in the study of</p> <p>10 whether a sling made from the mesh -- a</p> <p>11 softer, lighter-weight, larger-core mesh,</p> <p>12 such as the Ultrapro, is a safer alternative</p> <p>13 design to the TVT or TVT-O?</p> <p>14 A That's correct.</p> <p>15 Q So, it's fair to say that you don't know</p> <p>16 whether or not those meshes have been</p> <p>17 demonstrated to be more safe or effective</p> <p>18 than the TVT or TVT-O, because you haven't</p> <p>19 looked at that question?</p> <p>20 A Correct.</p> <p>21 Q Do you believe that a design or a mesh has</p> <p>22 to be studied for as long or in the same</p> <p>23 number of patients before it can be</p> <p>24 demonstrated to be as safe or effective as</p>
<p style="text-align: right;">Page 211</p> <p>1 A Yes.</p> <p>2 Q What other treatment options do you believe</p> <p>3 they're reasonably safe in comparison to?</p> <p>4 A Burch.</p> <p>5 Q Any others?</p> <p>6 A Bladder neck sling.</p> <p>7 Q When you say "bladder neck sling," are you</p> <p>8 referring to, like, an autologous fascial</p> <p>9 sling with either the patient's own tissue</p> <p>10 or cadaveric fascia?</p> <p>11 A Yes. Bladder neck, where it says</p> <p>12 midurethral, two different locations.</p> <p>13 Q One of your other opinions is that no other</p> <p>14 design or mesh has been demonstrated to be</p> <p>15 more effective, safer, or has been studied</p> <p>16 as much, as long, or in as many patients or</p> <p>17 types of patients as the TVT has showing</p> <p>18 it's safe and effective and the TVT and the</p> <p>19 TVT-O" -- actually, that's where I wanted to</p> <p>20 stop. Let me strike that and see if I can</p> <p>21 ask a better question.</p> <p>22 Is it going to be one of the opinions</p> <p>23 that you'll offer in this case that no other</p> <p>24 design or mesh has been demonstrated to be</p>	<p style="text-align: right;">Page 213</p> <p>1 the TVT and TVT-O?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: I don't</p> <p>5 understand the question.</p> <p>6 BY MR. FAES:</p> <p>7 Q First of all, one of the opinions that</p> <p>8 you're giving is that the TVT and TVT-O</p> <p>9 devices are one of the most studied devices</p> <p>10 out there; right?</p> <p>11 A Correct.</p> <p>12 Q When you give that opinion, are you</p> <p>13 referring to the number of patients, the</p> <p>14 length of the studies, or both?</p> <p>15 A I'm not sure what you're asking me here.</p> <p>16 Q Well, let me maybe ask it in a way that you</p> <p>17 can answer.</p> <p>18 What do you mean when you give the</p> <p>19 opinion that no device has been studied as</p> <p>20 much or as long in patients as the TVT or</p> <p>21 TVT-O?</p> <p>22 A I don't know if any other stress urinary</p> <p>23 incontinence treatment has been researched</p> <p>24 more than the TVT sling. I don't think</p>

<p style="text-align: right;">Page 214</p> <p>1 there's any other methods of treatment that</p> <p>2 have as many scientific and peer-reviewed</p> <p>3 articles about it as this.</p> <p>4 Q So, is it your opinion that TVT and TVT-O</p> <p>5 devices have the best quality of studies?</p> <p>6 A I didn't say that. They have the highest</p> <p>7 number of studies and many of them are very</p> <p>8 good quality studies.</p> <p>9 Q So, you're not going to give an opinion in</p> <p>10 this case that the TVT or the TVT-O has the</p> <p>11 highest quality of studies of any stress</p> <p>12 urinary incontinence device out there, just</p> <p>13 the highest number?</p> <p>14 A By far, they have been the most studied</p> <p>15 method in incontinence in the world, in the</p> <p>16 industry.</p> <p>17 Q But just so we're clear, you're not giving</p> <p>18 any opinion that they have the highest</p> <p>19 quality of studies?</p> <p>20 A That, I can't say. I don't have an opinion</p> <p>21 about that right now. That's a whole</p> <p>22 different research.</p> <p>23 Q So, I guess what I'm trying to get at, is it</p> <p>24 possible for another design or another mesh</p>	<p style="text-align: right;">Page 216</p> <p>1 A Yeah, I would think so. Adequate -- it's --</p> <p>2 I would think so, yeah. They list probably</p> <p>3 most of it if not all of it.</p> <p>4 Q So, when you give that opinion, which IFU</p> <p>5 are you referring to, from which time</p> <p>6 period?</p> <p>7 A There are a couple different ones. I would</p> <p>8 tie the package insert to a time when it was</p> <p>9 used.</p> <p>10 Q You understand that there have been multiple</p> <p>11 versions of both the TVT and TVT-O IFU over</p> <p>12 the years; right?</p> <p>13 A Yes.</p> <p>14 Q And is it going to be your opinion that any</p> <p>15 one of those TVT IFUs, or instructions for</p> <p>16 use, were sufficient to warn physicians --</p> <p>17 A No. There's one from 2015 and after. You</p> <p>18 can't apply that to 2005 because there's</p> <p>19 more information coming along always. If</p> <p>20 they update it, it's for a reason. There's</p> <p>21 new or more information. No, I don't think</p> <p>22 you can mix them.</p> <p>23 Q So, what are you relying on for your opinion</p> <p>24 that the TVT and TVT-O IFUs are adequate to</p>
<p style="text-align: right;">Page 215</p> <p>1 to be demonstrated to be more safe or</p> <p>2 effective than the TVT or TVT-O without</p> <p>3 having the same number or quantity of</p> <p>4 studies as the TVT and TVT-O device has?</p> <p>5 A It's possible.</p> <p>6 Q So, one of the opinions that you intend to</p> <p>7 offer in this case is that the TVT and TVT-O</p> <p>8 IFUs are adequate to warning of the risks of</p> <p>9 the TVT and TVT-O devices; is that accurate?</p> <p>10 A Say that again.</p> <p>11 Q Is one of the opinions that you intend to</p> <p>12 offer in this case is that the IFU, or the</p> <p>13 instructions for use, of the TVT and TVT-O</p> <p>14 are adequate to warn for the risks in those</p> <p>15 devices?</p> <p>16 A I don't quite understand the question. The</p> <p>17 package insert lists a lot of warnings, yes.</p> <p>18 I don't quite understand what you're asking</p> <p>19 about.</p> <p>20 Q You're offering an opinion in this case that</p> <p>21 the IFU, or instructions for use --</p> <p>22 A Yes.</p> <p>23 Q -- are adequate to inform physicians of</p> <p>24 those risks; right?</p>	<p style="text-align: right;">Page 217</p> <p>1 warn of those risks? What standard are you</p> <p>2 applying?</p> <p>3 MS. VAN STEENBURGH: Object to</p> <p>4 form.</p> <p>5 THE WITNESS: I don't know if</p> <p>6 the way you worded it is the way I would word</p> <p>7 it -- answer that. The package insert is a</p> <p>8 listing of a lot of different things that can</p> <p>9 happen. You can't, for example, start</p> <p>10 inserting those things by just reading the</p> <p>11 packaging. It is a list of warnings. It's</p> <p>12 in just about anything we buy nowadays,</p> <p>13 there's a listing. There always are.</p> <p>14 BY MR. FAES:</p> <p>15 Q So, for the TVT-O and the TVT devices, what</p> <p>16 adverse reactions do you think need to be</p> <p>17 included in the IFU or instructions for use?</p> <p>18 A You want the whole list? Pull out the list</p> <p>19 and look at them. That list is important at</p> <p>20 two times. One is when you decide you want</p> <p>21 to start using this product, you need to</p> <p>22 study it. The other one is when you want to</p> <p>23 talk to the patient. And I don't think</p> <p>24 necessarily you have to sit and discuss</p>

<p style="text-align: right;">Page 218</p> <p>1 every detail that's listed in the packaging.</p> <p>2 But there are certain things you should</p> <p>3 certainly discuss.</p> <p>4 Q In your practice, do you read the IFU for</p> <p>5 each mesh device before using it for the</p> <p>6 first time?</p> <p>7 A The first time? Yeah.</p> <p>8 Q Okay. When you read an IFU, or instructions</p> <p>9 for use, do you assume that the IFU is</p> <p>10 disclosing to you all of the risks and</p> <p>11 complications that the company knew could</p> <p>12 occur with the device that you're using?</p> <p>13 MS. VAN STEENBURGH: Object to</p> <p>14 form.</p> <p>15 THE WITNESS: I would never</p> <p>16 rely on that paper for that information for</p> <p>17 everything for inserting a sling. You have</p> <p>18 to go through a learning process. You have</p> <p>19 to read papers and books and go to class and</p> <p>20 talk to peers. It's a long process before</p> <p>21 you independently put those in a patient.</p> <p>22 The whole process is important, not just the</p> <p>23 packages.</p> <p>24</p>	<p style="text-align: right;">Page 220</p> <p>1 companies, though; is that right?</p> <p>2 A I do. I have.</p> <p>3 Q What other medical device companies have you</p> <p>4 consulted for?</p> <p>5 A I have done a little bit of work with --</p> <p>6 what is the one that closed? AMS.</p> <p>7 Q American Medical Systems?</p> <p>8 A Yeah, yeah. I've done a little bit of work</p> <p>9 for them.</p> <p>10 Q Okay. Anybody else?</p> <p>11 A It's possible, but I can't recall. I</p> <p>12 haven't done much of that work at all,</p> <p>13 but -- oh, yeah. Da Vinci robot, I've been</p> <p>14 a trainer for them.</p> <p>15 Q Yeah. I think that's actually on your CV,</p> <p>16 that you're a trainer for the company that</p> <p>17 makes the da Vinci surgical robot; right?</p> <p>18 A Yeah.</p> <p>19 Q Any other medical device companies or</p> <p>20 pharmaceutical companies, for that matter,</p> <p>21 that you've done consulting for?</p> <p>22 A No pharmaceutical. Device, I can't recall</p> <p>23 now. If it's in my list. But I can't</p> <p>24 recall.</p>
<p style="text-align: right;">Page 219</p> <p>1 BY MR. FAES:</p> <p>2 Q Do you feel like a physician should be able</p> <p>3 to rely on the IFU, or instructions for use,</p> <p>4 as a complete source of all the adverse</p> <p>5 events that may occur with a particular</p> <p>6 medical device?</p> <p>7 A I don't know what the legality is of that.</p> <p>8 I think personally, yeah. But if there's</p> <p>9 any serious complication or risk, it should</p> <p>10 be in the document, because I would want to</p> <p>11 know that. But sometimes there's too much</p> <p>12 information in there. You don't always know</p> <p>13 what to rely on and what is for real and</p> <p>14 what is possible but not hardly ever seen.</p> <p>15 Q I may have asked this earlier and I</p> <p>16 apologize if I did.</p> <p>17 Have you ever -- it's true that</p> <p>18 you've never helped draft an IFU, or</p> <p>19 instructions for use; right?</p> <p>20 A No, no.</p> <p>21 Q You've never worked for a medical device</p> <p>22 company on an IFU?</p> <p>23 A Never.</p> <p>24 Q You have consulted for other medical device</p>	<p style="text-align: right;">Page 221</p> <p>1 Q What list are you referring to?</p> <p>2 A My CV. I can't -- I don't think I have.</p> <p>3 Q Have you ever done any kind of educational</p> <p>4 talks or anything like that on behalf of</p> <p>5 pharmaceutical companies for overactive</p> <p>6 bladder medications or anything like that?</p> <p>7 A No. I have had -- I had a meeting with --</p> <p>8 yes, two things. It was Coloplast. I made</p> <p>9 a recommendation to taper the Y-Mesh they</p> <p>10 have. And that's called Restorelle, I</p> <p>11 think. And I met with an engineer from</p> <p>12 there and they did come out with a version</p> <p>13 that was a little tapered. I was just</p> <p>14 involved with that.</p> <p>15 There's a hydraulic arm that holds a</p> <p>16 vaginal or uterine manipulator. It's</p> <p>17 attached to that. I was involved with some</p> <p>18 feedback and advice and testing of a new</p> <p>19 arm. And that's a -- I forget. Cooper</p> <p>20 Surgical. I didn't get any money from them.</p> <p>21 I think I got a dinner and a bottle of wine.</p> <p>22 Besides that, I haven't done any work</p> <p>23 for any company.</p> <p>24 Q As you sit here today, do you have an</p>

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<p>1 understanding of any standard whatsoever as</p> <p>2 to what risks and complications are supposed</p> <p>3 to be disclosed in an IFU, or instructions</p> <p>4 for use?</p> <p>5 MS. VAN STEENBURGH: Object to</p> <p>6 form.</p> <p>7 THE WITNESS: I don't know</p> <p>8 anything about how they design and what needs</p> <p>9 to go in.</p> <p>10 BY MR. FAES:</p> <p>11 Q So, it's true then that you're not relying</p> <p>12 on any objective standard from any source</p> <p>13 regarding what should or shouldn't be</p> <p>14 included in an IFU with regard to risks?</p> <p>15 MS. VAN STEENBURGH: Object to</p> <p>16 form.</p> <p>17 THE WITNESS: I don't know the</p> <p>18 answer to that, no.</p> <p>19 BY MR. FAES:</p> <p>20 Q So, when you state that the TVT and the</p> <p>21 TVT-O IFUs are adequate to warn of the</p> <p>22 risks, you just mean that they're adequate</p> <p>23 to warn you personally, or do you think that</p> <p>24 they're adequate to warn all physicians?</p>	<p>1 that?</p> <p>2 MS. VAN STEENBURGH: The expert</p> <p>3 report, page 2.</p> <p>4 BY MR. FAES:</p> <p>5 Q So, it states, "the TVT and TVT-O IFU are</p> <p>6 adequate to warn of the risks of the TVT and</p> <p>7 TVT-O devices discussed below."</p> <p>8 Do you see that?</p> <p>9 A Yes.</p> <p>10 MS. VAN STEENBURGH: Counsel,</p> <p>11 he also used the word "sufficient."</p> <p>12 BY MR. FAES:</p> <p>13 Q Is there a difference, in your mind, as to</p> <p>14 "adequate" and "sufficient"?</p> <p>15 A It depends on how you interpret it.</p> <p>16 Adequate to warn. But that doesn't package</p> <p>17 the whole story. It's a sheet. It's a</p> <p>18 list. You can't use it to insert equipment.</p> <p>19 You have to be aware of it. You have to</p> <p>20 read it. It's a warning list, basically.</p> <p>21 Q Right. Is one of the opinions that you're</p> <p>22 going to offer in this case is that the</p> <p>23 warnings in the TVT and TVT-O IFU are</p> <p>24 adequate to warn of the risks?</p>
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<p>1 A Well, I didn't use the word "adequate." The</p> <p>2 way I see it, it's a listing of things that</p> <p>3 can go wrong, but it's up to me to research</p> <p>4 it further. I look at it more as a list of</p> <p>5 dangers than complete information. I don't</p> <p>6 know how they design them or legally what</p> <p>7 goes in them. The way I use them, I look at</p> <p>8 them for what warnings they have for me.</p> <p>9 Q So, you don't think that you used the term</p> <p>10 "adequate" to discuss the risks that are</p> <p>11 listed in the TVT and TVT-O instructions for</p> <p>12 use?</p> <p>13 A Well, my general experience in life with</p> <p>14 package inserts are that they list a lot of</p> <p>15 things, and I don't use them in practical</p> <p>16 life that much. I have to go to other</p> <p>17 sources to really find out the details about</p> <p>18 it. I look at them more as a list.</p> <p>19 Q So, let me go to page 2 of your report, the</p> <p>20 last half of the steps in the Disclosure of</p> <p>21 Opinions.</p> <p>22 MS. VAN STEENBURGH: Look at</p> <p>23 that.</p> <p>24 THE WITNESS: Which one is</p>	<p>1 A If you talk about adequate in actual listing</p> <p>2 everything, I think so; but they're not</p> <p>3 complete information, that they're an</p> <p>4 adequate list of information.</p> <p>5 Q So adequate to who? To you or to any</p> <p>6 physician?</p> <p>7 A To me. To me, yes.</p> <p>8 Q Okay. So, you're not --</p> <p>9 A I don't expect them to leave out anything</p> <p>10 serious, like this can kill you. It has to</p> <p>11 be in there. So, when I read it, I see all</p> <p>12 that's in there. But I need to know way</p> <p>13 more than that. I have to research some of</p> <p>14 these things. I read about them.</p> <p>15 Q So, you're not offering any opinions in this</p> <p>16 case as to whether or not the warnings in</p> <p>17 the adverse reaction section of the TVT and</p> <p>18 TVT-O IFU are adequate to other physicians.</p> <p>19 MS. VAN STEENBURGH: Object to</p> <p>20 form.</p> <p>21 THE WITNESS: I think we're</p> <p>22 talking past each other. I think package</p> <p>23 inserts sometimes list almost too much. It's</p> <p>24 hard sometimes to distinguish between what is</p>

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<p>1 important or not because everything is listed</p> <p>2 in there. So, my experience, it's not that</p> <p>3 they leave out things. It's just that</p> <p>4 there's almost too much.</p> <p>5 BY MR. FAES:</p> <p>6 Q Right. My question is: Are you going to</p> <p>7 offer an opinion in this case that the TVT</p> <p>8 and TVT-O IFU are adequate to warn other</p> <p>9 physicians of the risks of those devices?</p> <p>10 A Yeah, I think it's adequate as far as</p> <p>11 listing all the different concerns. I think</p> <p>12 I've been talking a little bit past you,</p> <p>13 because what I'm thinking is that whole</p> <p>14 relevant is that list. Sometimes it's</p> <p>15 difficult for me to interpret because</p> <p>16 there's too much information, too many</p> <p>17 things. They list everything. Everything</p> <p>18 is in there. While it's probably a good</p> <p>19 thing, but it's hard to decipher it</p> <p>20 sometimes.</p> <p>21 Q So, I guess my question, which I don't think</p> <p>22 I quite got an answer to earlier, is: Are</p> <p>23 you offering an opinion that the IFU for the</p> <p>24 TVT and TVT-O -- strike that.</p>	<p>1 A No.</p> <p>2 Q And you haven't done that analysis of what</p> <p>3 they knew or didn't know in, say, 2010?</p> <p>4 A No.</p> <p>5 Q Or any other year; correct?</p> <p>6 A No.</p> <p>7 Q Okay. So, do you believe that the adverse</p> <p>8 reactions section of the TVT IFU needs to</p> <p>9 include a warning for acute and/or chronic</p> <p>10 pain in order to be adequate?</p> <p>11 MS. VAN STEENBURGH: Why don't</p> <p>12 we -- do you have one? Are you saying it's</p> <p>13 not in there?</p> <p>14 MR. FAES: I'm just asking as</p> <p>15 he sits here today.</p> <p>16 BY MR. FAES:</p> <p>17 Q Do you think that needs to be included in</p> <p>18 the IFU, or instructions for use, in order</p> <p>19 to be adequate?</p> <p>20 A Acute pain?</p> <p>21 Q Yes.</p> <p>22 A I would think so, yeah.</p> <p>23 Q You think it needs to be included in there?</p> <p>24 A Yeah.</p>
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<p>1 Are you offering an opinion that the</p> <p>2 adverse reactions section of the TVT and</p> <p>3 TVT-O IFU was adequate for other physicians</p> <p>4 at all times that the products have been on</p> <p>5 the market?</p> <p>6 A I would think so.</p> <p>7 Q You would think so or --</p> <p>8 A I would think so. I think all</p> <p>9 information -- all the warnings are there,</p> <p>10 but like I said, sometimes there's too much</p> <p>11 there.</p> <p>12 Q Do you think so to a reasonable degree of</p> <p>13 medical certainty?</p> <p>14 A Yes.</p> <p>15 Q Have you engaged in any kind of study or</p> <p>16 formal analysis of what other physicians</p> <p>17 knew about the risks of the TVT and TVT-O</p> <p>18 devices at any particular times during the</p> <p>19 17-year history of the marketing of the TVT?</p> <p>20 A No, no.</p> <p>21 Q So, for example, you haven't done any kind</p> <p>22 of study or formal analysis to see what</p> <p>23 risks of the TVT or the TVT-O physicians who</p> <p>24 might implant that device know of today?</p>	<p>1 Q Do you think it needed to be included in</p> <p>2 there at all times that the company marketed</p> <p>3 the device, that the company was aware that</p> <p>4 was a risk?</p> <p>5 A I don't know how far back they were aware of</p> <p>6 it.</p> <p>7 Q But you'd agree as soon as they -- once they</p> <p>8 were aware that that was a potential adverse</p> <p>9 event of the TVT or TVT-O, they needed to</p> <p>10 include that as a potential adverse event in</p> <p>11 the IFU; right?</p> <p>12 A Probably.</p> <p>13 Q Do you think that pain with intercourse,</p> <p>14 which in some patients may not resolve, is a</p> <p>15 necessary risk that needs to be included in</p> <p>16 the TVT instructions for use?</p> <p>17 MS. VAN STEENBURGH: Object to</p> <p>18 form.</p> <p>19 THE WITNESS: That's something</p> <p>20 that can be discussed, I think, because I</p> <p>21 think pain with intercourse can be so many</p> <p>22 things. It can be a hard thing to evaluate.</p> <p>23 To put it in there that any time -- well, I</p> <p>24 don't know if I would include that in there</p>

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<p>1 because it's such a wide spectrum of things 2 that can cause that. I would hate to tie it 3 down to a sling. 4 Most people I see that have pain with 5 intercourse never have a sling. Would a 6 person with a sling have the same pain? It 7 isn't necessarily the sling that causes it. 8 It has to be evaluated. I don't know how 9 important it is to put that in there. 10 BY MR. FAES: 11 Q So, if I understand you correctly, you don't 12 think that specifically pain with 13 intercourse needs to be in the adverse 14 reactions section of the IFU in order for it 15 to be adequate? 16 A You may want to put it in there. But on the 17 other hand, I don't think it has anything to 18 do with safety. I don't think it's that big 19 a part of a discussion before putting in a 20 sling because there's so many other things 21 that cause pain with intercourse. I 22 wouldn't pull it out as a big deal before 23 putting in a sling. Most people getting 24 slings don't have pain with intercourse. I</p>	<p>1 now but shouldn't have been there in, say, 2 2010? 3 A I didn't say it shouldn't be back then. I 4 don't know enough to know whether -- I don't 5 know how much they knew about it back then. 6 I just don't know. 7 Q Well, assuming that Ethicon and 8 Johnson & Johnson knew that that was a 9 potential adverse event since the launch of 10 the TVT-O in 2003, do you think that that 11 adverse event should have been included in, 12 say, 2008 or 2009? 13 A I can't answer that. 14 Q Why don't you answer that? 15 A I don't have enough information. 16 Q What information would you need to have in 17 order to answer the question? 18 A I think it's in there now. I think it 19 should be in there. I think there's enough 20 known about it now. The problem is in the 21 past, there's so many things in there. We 22 learn things every day. I'm sure -- what 23 they should have done or could have done in 24 the past, I just can't make a statement on</p>
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<p>1 don't even know if people with slings have 2 more pain than people without slings. 3 That's something that needs to be discussed. 4 I don't know if it's there or not. 5 Q Do you think that the TVT and the TVT-O IFU 6 needs to include a warning regarding 7 neuromuscular problems, including acute 8 and/or chronic pain in the groin, thigh, 9 leg, pelvic, and/or abdominal area in order 10 for it to be adequate? 11 A Isn't that in there? I can't recall that. 12 I would have to look at it. 13 Q Well, it's in there now. 14 A I think it should be in there. I think I've 15 seen it in there. 16 Q Do you think that it should have been 17 included in the IFU, or instructions for 18 use, as soon as the company was aware that 19 that was a potential adverse event? 20 A I don't know about that. I can't answer 21 that. In the past, no. I think it is in 22 there now and I think it should be in there, 23 if I recall it right. 24 Q So, why do you think it should be in there</p>	<p>1 that. 2 Q So, you're not offering an opinion in this 3 case as to whether or not Ethicon and 4 Johnson & Johnson should have included that 5 statement in the IFU earlier than when it 6 was added in 2015? 7 A I don't know enough about it to make an 8 opinion about that. I would have to see 9 what was available and what was known. I 10 just don't know that. 11 MR. FAES: We have about 44 12 minutes left. Do you want to take a quick 13 break? 14 MS. VAN STEENBURGH: Sure. 15 (Recess began - 2:13 p.m.) 16 (Recess ended - 2:22 p.m.) 17 BY MR. FAES: 18 Q Doctor, we're back on the record after a 19 short break. We were talking about the 20 adverse reaction section of the TVT products 21 instructions for use. 22 Do you remember that? 23 A Yes. 24 Q Do you feel that in order for the IFU for</p>

<p style="text-align: right;">Page 234</p> <p>1 the TVT and TVT-O to be adequate, that it</p> <p>2 needs to contain a warning about urge</p> <p>3 incontinence in order for it to be adequate?</p> <p>4 A Yeah.</p> <p>5 Q And do you believe that that's true, that it</p> <p>6 should have been included as soon as Ethicon</p> <p>7 and Johnson & Johnson was --</p> <p>8 A I think it is included, isn't it?</p> <p>9 Q Let me finish my question.</p> <p>10 A Yeah.</p> <p>11 Q Do you believe that that should have been</p> <p>12 included in the IFU as soon as Ethicon and</p> <p>13 Johnson & Johnson was aware that that was a</p> <p>14 potential adverse effect?</p> <p>15 A I can't answer to that at all. I cannot. I</p> <p>16 think it is in there. I think I've seen it</p> <p>17 in there. In the past, I don't know.</p> <p>18 Q Okay. So, you don't know if it --</p> <p>19 Do you have an opinion as to whether</p> <p>20 or not it should have been included in the</p> <p>21 IFU once Ethicon and Johnson & Johnson was</p> <p>22 aware of it?</p> <p>23 A I don't have any information about what they</p> <p>24 were aware of and when. I can't say</p>	<p style="text-align: right;">Page 236</p> <p>1 A Were they totally aware of it or had</p> <p>2 suspicion of it or strong proof of it, I</p> <p>3 don't know. I don't have an opinion about</p> <p>4 that. I have no information to base it on.</p> <p>5 Q And what about urinary retention? Do you</p> <p>6 think urinary retention needs to be</p> <p>7 included --</p> <p>8 A Yes.</p> <p>9 Q Let me get the whole question out.</p> <p>10 Do you think that urinary retention</p> <p>11 needs to be included as a potential adverse</p> <p>12 event of the TVT and TVT-O in order for the</p> <p>13 IFU to be adequate?</p> <p>14 A At this point, yes.</p> <p>15 Q At what point do you think it was necessary</p> <p>16 for it to be included in the IFU or</p> <p>17 instructions for use?</p> <p>18 A I don't know if they knew about it in the</p> <p>19 past. I can't pass judgment on that.</p> <p>20 (Exhibit No. 19 Marked.)</p> <p>21</p> <p>22 BY MR. FAES:</p> <p>23 Q Doctor, I'm going to hand you what's been</p> <p>24 marked as Exhibit No. 19 to your deposition.</p>
<p style="text-align: right;">Page 235</p> <p>1 anything about that.</p> <p>2 Q I understand. But assuming that they were</p> <p>3 aware of it since the product was launched</p> <p>4 in 1998, do you think that that should have</p> <p>5 been included in the IFU, or instructions</p> <p>6 for use?</p> <p>7 MS. VAN STEENBURGH: Object to</p> <p>8 form.</p> <p>9 THE WITNESS: I don't have an</p> <p>10 opinion on that.</p> <p>11 BY MR. FAES:</p> <p>12 Q Do you have an opinion as to whether or not</p> <p>13 the adverse reaction of urinary frequency</p> <p>14 needs to be included in the IFU for the TVT</p> <p>15 products in order for the warnings to be</p> <p>16 adequate?</p> <p>17 A Yeah, probably.</p> <p>18 Q And I assume the answer to my question is</p> <p>19 the same as the previous one, that you don't</p> <p>20 have any opinion as to whether or not it</p> <p>21 should have been included in the</p> <p>22 instructions for use since its launch if</p> <p>23 Ethicon was aware that that was a potential</p> <p>24 risk?</p>	<p style="text-align: right;">Page 237</p> <p>1 And this is Minnesota Physician dated</p> <p>2 December of 2013.</p> <p>3 Have you seen this document before?</p> <p>4 A Yes.</p> <p>5 Q And, in fact, you wrote an article that</p> <p>6 appears in this publication; right?</p> <p>7 A Let me see here.</p> <p>8 Q It starts on page 24, I think.</p> <p>9 A (Witness reviews the document.)</p> <p>10 Yes.</p> <p>11 Q So, this is an article that you wrote in</p> <p>12 November of 2013; right?</p> <p>13 A That's correct.</p> <p>14 Q This isn't an article that's listed or</p> <p>15 disclosed in your CV; right?</p> <p>16 A I can't recall that. I had forgotten this</p> <p>17 article, so it may not be in there.</p> <p>18 Q Does this article refresh your recollection</p> <p>19 as to any other articles that you may have</p> <p>20 written that aren't disclosed in your CV?</p> <p>21 A No, there are no other ones.</p> <p>22 Q I want to ask you some things that you wrote</p> <p>23 in this, starting at the bottom right-hand</p> <p>24 corner of the page 24. You write,</p>

<p style="text-align: right;">Page 238</p> <p>1 "Sometimes mesh is used to hold up the 2 vagina in an attempt to reduce incontinence. 3 For many women, this mesh offered a good 4 solution, but others experienced significant 5 scarring and pain, necessitating mesh 6 removal and surgery to reconstruct the 7 anatomy"; correct? 8 A Yeah. That's correct. 9 Q Is that a statement that you stand by today? 10 A Yes. 11 Q It goes on to state, "Recently, the U.S. 12 government issued warnings about the use of 13 certain transvaginal nylon mesh use in the 14 treatment of urinary incontinence." 15 Do you see that? 16 A Where was that again? 17 Q It's going to the following page. It 18 states, "Recently, the U.S. government 19 issued warnings about the use of certain 20 transvaginal nylon mesh used in the 21 treatment of urinary incontinence." 22 Do you see that? 23 A Yes. 24 Q What are you referring to? What nylon mesh?</p>	<p style="text-align: right;">Page 240</p> <p>1 A Right. 2 Q And you use that frequently for mesh 3 removal; is that right? 4 A When I do remove mesh, I usually nowadays 5 use the da Vinci, yes. Not all the time. 6 Most of the time. 7 Q Do you still use, for instance, Metzenbaum 8 scissors sometimes to remove mesh, or is it 9 pretty much always the robot that you use? 10 A Metzenbaum scissors? 11 Q Yeah. 12 A In the vagina, yes. But if it's in the 13 pelvis, I use the robot. 14 Q And then it goes on to state, "In the past, 15 the mesh was inserted vaginally. Every time 16 a physician operates through the vagina, he 17 or she needs a seam allowance and the vagina 18 gets smaller." 19 A That's correct. 20 Q And that's a true statement today, that 21 every time that mesh is inserted vaginally, 22 the vagina gets smaller or shortens; right? 23 A Correct. 24 Q Do you think that's a potential risk that</p>
<p style="text-align: right;">Page 239</p> <p>1 A Well, it's -- any -- I can't remember any 2 specific -- which one I was thinking about 3 at that time. It would probably relate to 4 any kind of mesh. 5 Q Is it possible that you meant to refer to 6 polypropylene mesh and not nylon mesh? 7 A Probably. 8 Q It goes on to state, "As a physician who has 9 performed a large number of these mesh 10 removals, I can attest to the fact that 11 removal can be tricky." 12 A That is correct. 13 Q And that's a correct statement today? 14 A Yes. 15 Q So, it's a correct statement that you're a 16 physician that's done a large number of 17 vaginal mesh removals for stress urinary 18 incontinence mesh? 19 A That's correct, yes. 20 Q And frequently, the removal can be tricky; 21 is that accurate? 22 A That's correct, yeah. 23 Q If you go -- and then it talks about the da 24 Vinci surgical robot that you use.</p>	<p style="text-align: right;">Page 241</p> <p>1 physicians should be made aware of, is that 2 there can be a vaginal shortening as a 3 result of the implant of a TVT or TVT-O 4 mesh? 5 MS. VAN STEENBURGH: Object to 6 form. 7 THE WITNESS: I think the 8 physicians have been aware of that, that the 9 vagina gets shorter and narrower with every 10 surgery, a long time before the mesh. 11 BY MR. FAES: 12 Q But my question is: Do you think that 13 that's a risk that needs to be included in 14 the TVT or TVT-O IFU in order for that IFU 15 to be adequate? 16 MS. VAN STEENBURGH: Object to 17 form. 18 THE WITNESS: I don't know 19 about that because any surgery -- any surgery 20 where you cut the vagina open, whether it's 21 mesh or not, will make the vagina smaller, 22 and that's been known forever. I don't think 23 that's new or different with mesh. It's not 24 the mesh in itself. It's the cutting through</p>

<p style="text-align: right;">Page 242</p> <p>1 the vaginal wall and sewing it up.</p> <p>2 BY MR. FAES:</p> <p>3 Q So -- well, first of all, you believe it's</p> <p>4 not the mesh itself that causes the vaginal</p> <p>5 shortening; right?</p> <p>6 A No. It's the cutting. When you cut and</p> <p>7 sew, every time, it's shorter, tighter.</p> <p>8 Q So, if, indeed, it were shown that the</p> <p>9 surgical mesh actually did cause or</p> <p>10 contribute to vaginal shortening in addition</p> <p>11 to just the cutting, do you think that's an</p> <p>12 adverse event that should be warned of in</p> <p>13 the TVT IFU in order for it to be adequate?</p> <p>14 MS. VAN STEENBURGH: Object to</p> <p>15 form.</p> <p>16 THE WITNESS: Possible.</p> <p>17 BY MR. FAES:</p> <p>18 Q And then it goes on to talk about the fact</p> <p>19 that you use -- now use the da Vinci robot</p> <p>20 to do ASC procedures and with that, that</p> <p>21 there's no further vaginal shrinkage making</p> <p>22 it a nice option to offer women; is that</p> <p>23 right?</p> <p>24 A That's right. You don't have to cut into</p>	<p style="text-align: right;">Page 244</p> <p>1 right?</p> <p>2 A Yes.</p> <p>3 Q So, you'd agree that the use of the</p> <p>4 procedure that you're describing here, which</p> <p>5 also includes the use of smaller pieces of</p> <p>6 mesh, results in less pain, bleeding, and</p> <p>7 scarring for the patient; right?</p> <p>8 MS. VAN STEENBURGH: Object to</p> <p>9 form.</p> <p>10 THE WITNESS: Right.</p> <p>11 BY MR. FAES:</p> <p>12 Q So, on page 8 of your expert report, if you</p> <p>13 can turn back to that, please, I'm going to</p> <p>14 ask you some questions about the section</p> <p>15 entitled "Alleged Complications Associated</p> <p>16 with TVT."</p> <p>17 A (Complying.)</p> <p>18 Q So, under Inflammation, you state on, I</p> <p>19 think it's the second sentence or third, you</p> <p>20 state, "In my practice, I have not</p> <p>21 experienced a chronic inflammatory response</p> <p>22 with TVT that resulted in clinical</p> <p>23 consequences such as pain."</p> <p>24 Do you see that?</p>
<p style="text-align: right;">Page 243</p> <p>1 the vagina.</p> <p>2 Q So, you agree that a procedure that doesn't</p> <p>3 involve cutting in the vagina is a nice</p> <p>4 option to offer women because you don't have</p> <p>5 that risk of vaginal shortening; right?</p> <p>6 MS. VAN STEENBURGH: Object to</p> <p>7 form.</p> <p>8 THE WITNESS: Right.</p> <p>9 BY MR. FAES:</p> <p>10 Q It goes on to state that "This procedure,</p> <p>11 combined with newer, smaller pieces of mesh,</p> <p>12 has become state-of-the-art repair for</p> <p>13 vaginal prolapse."</p> <p>14 Do you see that?</p> <p>15 A That's correct.</p> <p>16 Q So, you'd agree that now for vaginal</p> <p>17 prolapse procedures, that you're trying to</p> <p>18 use smaller pieces of mesh or the least</p> <p>19 amount of mesh possible to get the job done;</p> <p>20 right?</p> <p>21 A That is correct.</p> <p>22 Q And it states that these "Minimally invasive</p> <p>23 surgeries result in faster recovery, along</p> <p>24 with less pain, bleeding, and scarring";</p>	<p style="text-align: right;">Page 245</p> <p>1 A Yes.</p> <p>2 Q Is that an opinion that you intend to offer</p> <p>3 in this case?</p> <p>4 A Yes.</p> <p>5 Q But as I think we discussed earlier, you</p> <p>6 can't state how many implants you've even --</p> <p>7 strike that.</p> <p>8 You can't state how many vaginal mesh</p> <p>9 implants you've actually removed in the</p> <p>10 course of your career; right?</p> <p>11 A No. I can't give you an exact number.</p> <p>12 Q Do you regularly review the -- strike that.</p> <p>13 First of all, is it your normal</p> <p>14 practice, when you remove or excise a</p> <p>15 vaginal mesh, to send that mesh to</p> <p>16 pathology?</p> <p>17 A Not always. Most of the stuff we take out</p> <p>18 goes to pathology. I'm not sure all the</p> <p>19 mesh pieces go.</p> <p>20 Q You don't know the percentage of cases of</p> <p>21 the mesh you send to pathology?</p> <p>22 A No.</p> <p>23 Q And do you know how many of those cases</p> <p>24 where the mesh was removed for pain, that</p>

<p style="text-align: right;">Page 246</p> <p>1 the pathology report indicated mild, 2 moderate, or chronic inflammation? 3 A No, I can't recall that. 4 Q So, you'd agree that this statement, that 5 you haven't experienced a chronic 6 inflammatory response in TVT that resulted 7 in clinical consequences such as pain, isn't 8 as a result of any kind of formalized 9 analysis of your patients or your patients' 10 medical records; correct? 11 A Yeah. 12 Q And you couldn't state with any kind of 13 certainty what percentages -- what 14 percentage of the patients are where you 15 removed a mesh due to pain and those 16 pathology reports indicated mild, moderate, 17 or chronic inflammation; right? 18 A That's correct. 19 Q It also states in this paragraph that in 20 your experience, "this inflammation remains 21 stable or contained in an area immediately 22 adjacent to the mesh and does not continue 23 to expand in size." 24 A That's correct.</p>	<p style="text-align: right;">Page 248</p> <p>1 of a defect or problem with the mesh? 2 MS. VAN STEENBURGH: Object to 3 form. 4 THE WITNESS: I haven't seen 5 that, so I wouldn't be able to make a 6 statement on a case that I recall seeing 7 that. 8 BY MR. FAES: 9 Q So, hypothetically, if you saw a TVT mesh 10 that was removed and the pathology report 11 showed chronic, ongoing inflammation that 12 was continuing even more than one year past 13 the implant, would that be indicative of a 14 problem to you with the mesh or with the 15 patient? 16 MS. VAN STEENBURGH: Object to 17 form. 18 THE WITNESS: The thing is when 19 you operate on people, you don't just go and 20 cut out tissue that looks normal. So, 21 there's no way I can say what looks normal to 22 me is not normal to you. If it looks normal, 23 we leave it. The affected tissue or whatever 24 it is seems to be right up on the mesh. It</p>
<p style="text-align: right;">Page 247</p> <p>1 Q What's that opinion based on? 2 A Say that again. 3 Q What's that opinion based on? 4 A The tissue around looks very soft and normal 5 and there's really a mark where the 6 inflammation is and no inflammation. You 7 can really see it. 8 Q So, this opinion is basically based on what 9 you see in general when you remove meshes? 10 A Yes. 11 Q If there is inflammation that isn't stable, 12 is that something that you would note in 13 your operative report? 14 A If I saw it, yeah. 15 Q Have you done any kind of formalized 16 analysis of your patients' records to see if 17 that was actually noted in any of their 18 records? 19 A No. 20 Q Would you agree that if a pathology report 21 or a formal analysis indicated that the 22 inflammation around the TVT mesh was, in 23 fact, not stable but was chronic and 24 ongoing, would that be an indication to you</p>	<p style="text-align: right;">Page 249</p> <p>1 doesn't spread out. And I can't just go and 2 cut tissue out of a person to prove that it's 3 normal. When it looks normal to me, I leave 4 it alone. 5 BY MR. FAES: 6 Q But you would agree that in order to know 7 for sure whether inflammation was chronic or 8 ongoing, you would need to actually have a 9 pathologist look at that mesh implant or the 10 tissue surrounding that mesh; right? 11 A That super narrow area right around the mesh 12 is a little fibrotic and it's hard. That 13 gets cut out and sent in. The normal tissue 14 around that we don't send in. It's very 15 limited what gets sent to pathology. 16 Q So, you would agree that in many cases when 17 you excise or remove a vaginal mesh, that a 18 lot of times there's fibrotic or hardened 19 tissue surrounding the mesh? 20 A Right on the mesh or in the mesh. There's 21 very little spread. 22 Q In your experience, can that fibrotic or 23 hard tissue surrounding the mesh cause pain 24 or discomfort for the patient?</p>

<p style="text-align: right;">Page 250</p> <p>1 A Do you want me to tell you what I see? Most</p> <p>2 of the mesh, if there's mesh and pain, it's</p> <p>3 because the mesh is not sitting right, it's</p> <p>4 sewed into the wrong thing, put in crooked,</p> <p>5 put in too tight. Mesh sitting normal, I</p> <p>6 have a hard time recalling anyone that hurt.</p> <p>7 Q You also go on to offer opinions regarding</p> <p>8 cytotoxicity in the following paragraph.</p> <p>9 Do you see that?</p> <p>10 A Yes.</p> <p>11 Q It states that "A study by Wang and his</p> <p>12 colleagues upon which they rely reporting a</p> <p>13 rate of persistent defective healing of 1</p> <p>14 percent has not been replicated in other</p> <p>15 clinical studies in women."</p> <p>16 Do you see that?</p> <p>17 A Right.</p> <p>18 Q So, have you seen any studies indicating</p> <p>19 that the rate of erosion or persistent</p> <p>20 defective healing with the TVT can be as</p> <p>21 high as 19 percent?</p> <p>22 MS. VAN STEENBURGH: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: That it can be</p>	<p style="text-align: right;">Page 252</p> <p>1 order for you to conclude that the TVT mesh</p> <p>2 may be cytotoxic?</p> <p>3 MS. VAN STEENBURGH: Object to</p> <p>4 form.</p> <p>5 THE WITNESS: Cytotoxic is</p> <p>6 something else. I don't believe Prolene is</p> <p>7 cytotoxic. We use Prolene in every operating</p> <p>8 room in every hospital in the country.</p> <p>9 There's been Prolene put in every day. I</p> <p>10 don't believe it's cytotoxic or we would know</p> <p>11 way more about it.</p> <p>12 BY MR. FAES:</p> <p>13 Q Well, you would agree with me that if the</p> <p>14 TVT mesh were cytotoxic, that that would</p> <p>15 indicate -- that that would be a defect with</p> <p>16 the product and that it shouldn't be used;</p> <p>17 right?</p> <p>18 MS. VAN STEENBURGH: Object to</p> <p>19 form.</p> <p>20 THE WITNESS: Yes. Or the</p> <p>21 material in the product. But I don't believe</p> <p>22 in that.</p> <p>23 BY MR. FAES:</p> <p>24 Q Right. It's not that you don't believe that</p>
<p style="text-align: right;">Page 251</p> <p>1 cytotoxicity?</p> <p>2 BY MR. FAES:</p> <p>3 Q No, no. That it can be -- that the rate of</p> <p>4 persistent defective healing or erosions</p> <p>5 with TVT has been as high as 19 percent.</p> <p>6 MS. VAN STEENBURGH: Object to</p> <p>7 form.</p> <p>8 THE WITNESS: No, I don't</p> <p>9 recall that. Erosion as high as 19 percent?</p> <p>10 BY MR. FAES:</p> <p>11 Q Yes.</p> <p>12 A I don't know what study that is, no.</p> <p>13 Q Have you ever reviewed the Tseng study,</p> <p>14 T-S-E-N-G study, comparing the TVT to the</p> <p>15 SPARC mesh?</p> <p>16 A I can't remember.</p> <p>17 Q Do you know whether or not the results of</p> <p>18 that study were actually reported on</p> <p>19 Ethicon's website at one time and reported</p> <p>20 the erosion rate as high as 19 percent?</p> <p>21 A No, I don't know that. That would be way</p> <p>22 higher than what I've seen in real life.</p> <p>23 Q What percentage of erosions or persistent</p> <p>24 defective healing would you need to see in</p>	<p style="text-align: right;">Page 253</p> <p>1 cytotoxicity is not a defect. You just</p> <p>2 don't believe that the TVT mesh is</p> <p>3 cytotoxic; correct?</p> <p>4 A I don't believe it's cytotoxic.</p> <p>5 Q Have you seen testing done by Ethicon and</p> <p>6 Johnson & Johnson in 1997 and in 1998 where</p> <p>7 the tests actually came back positive for</p> <p>8 cytotoxicity on the TVT mesh?</p> <p>9 A No, I haven't.</p> <p>10 Q Is that information that you would want to</p> <p>11 see before forming your opinions in this</p> <p>12 case?</p> <p>13 MS. VAN STEENBURGH: Object to</p> <p>14 form.</p> <p>15 THE WITNESS: I have seen other</p> <p>16 discussions of this and I thought it was</p> <p>17 pretty much decided that it was not</p> <p>18 cytotoxic. I can't cite every study. I</p> <p>19 would like to see it if it's relevant. But</p> <p>20 so far, I don't believe it.</p> <p>21 BY MR. FAES:</p> <p>22 Q Well, one of the opinions that you give in</p> <p>23 your expert report is that Ethicon</p> <p>24 extensively studied cytotoxicity and its</p>

<p style="text-align: right;">Page 254</p> <p>1 results satisfied the FDA that the mesh was</p> <p>2 not cytotoxic.</p> <p>3 A Right.</p> <p>4 Q Is that an opinion that you intend to offer</p> <p>5 in this case?</p> <p>6 A Yes.</p> <p>7 Q How do you know that the FDA was satisfied</p> <p>8 that the mesh was not cytotoxic?</p> <p>9 A I haven't seen anything to the fact that</p> <p>10 they were not satisfied.</p> <p>11 Q Well, do you know if Ethicon and Johnson &</p> <p>12 Johnson ever shared the results of the 1997</p> <p>13 or 1998 studies that they did on the TVT</p> <p>14 mesh that showed it was cytotoxic?</p> <p>15 A If they didn't share it, I wouldn't have</p> <p>16 known it.</p> <p>17 Q So, you don't know whether or not if they'd</p> <p>18 actually shared that with the FDA, that the</p> <p>19 FDA would not have been satisfied that the</p> <p>20 mesh was cytotoxic?</p> <p>21 A I don't know about that.</p> <p>22 Q Do you even know what standards or what</p> <p>23 kinds of things the FDA relies on or</p> <p>24 requires in order to determine that a</p>	<p style="text-align: right;">Page 256</p> <p>1 directors are just wrong about that?</p> <p>2 MS. VAN STEENBURGH: Objection.</p> <p>3 THE WITNESS: No. Let me take</p> <p>4 a look here.</p> <p>5 I believe -- I've seen the number 30</p> <p>6 percent, and I believe that when you put a</p> <p>7 mesh in and it gives you no injury, that</p> <p>8 there's some shrinkage of the tissue. I</p> <p>9 don't think the mesh shrinks. I can't</p> <p>10 imagine how the mesh would shrink. But the</p> <p>11 tissue shrinks. And we know that. That's a</p> <p>12 consideration when we operate.</p> <p>13 BY MR. FAES:</p> <p>14 Q Well, if the tissue surrounding the mesh</p> <p>15 shrinks, it would take the mesh along it;</p> <p>16 right?</p> <p>17 A Yes.</p> <p>18 Q And it would encapsulate it.</p> <p>19 A Yes.</p> <p>20 Q That's how the mesh would shrink; right?</p> <p>21 A Right.</p> <p>22 Q So, would you agree that the shrinkage of</p> <p>23 mesh inside the contracted tissue could</p> <p>24 potentially entrap nerves which can cause</p>
<p style="text-align: right;">Page 255</p> <p>1 material is or isn't cytotoxic?</p> <p>2 A No.</p> <p>3 Q Do you know what ISO testing is?</p> <p>4 A No.</p> <p>5 Q Okay. Do you know what testing that -- as</p> <p>6 you sit here today, what testing Ethicon and</p> <p>7 Johnson & Johnson did on the TVT device in</p> <p>8 order to demonstrate that it was not</p> <p>9 cytotoxic?</p> <p>10 A No.</p> <p>11 Q So, on the next page, you discuss</p> <p>12 contraction of the mesh and you state in</p> <p>13 your experience, "the TVT mesh does not</p> <p>14 curl, rope, shrink, contract, or experience</p> <p>15 poor collapse when implanted as directed in</p> <p>16 the IFU."</p> <p>17 Do you see that?</p> <p>18 A Yes, I do.</p> <p>19 Q First of all, have you ever seen documents</p> <p>20 from Ethicon's own medical directors</p> <p>21 indicating that the mesh shrinks 30 percent</p> <p>22 as a rule of thumb?</p> <p>23 A Yes. I have seen that number.</p> <p>24 Q Do you believe that Ethicon's medical</p>	<p style="text-align: right;">Page 257</p> <p>1 pain for the patient?</p> <p>2 MS. VAN STEENBURGH: Object to</p> <p>3 form.</p> <p>4 THE WITNESS: If there were</p> <p>5 nerves in the area. You would have to put a</p> <p>6 nerve in there first.</p> <p>7 BY MR. FAES:</p> <p>8 Q Isn't the pelvic floor a ready source of</p> <p>9 nerves in the human body?</p> <p>10 MS. VAN STEENBURGH: Object to</p> <p>11 form.</p> <p>12 THE WITNESS: Yeah. It's not</p> <p>13 really where you put the slings. There are</p> <p>14 no major nerves there. You're talking about</p> <p>15 the slings.</p> <p>16 BY MR. FAES:</p> <p>17 Q Do you think that -- strike that.</p> <p>18 Can the contracture surrounding a</p> <p>19 mesh which, in turn, takes the mesh with it</p> <p>20 in the contracture, do you believe that that</p> <p>21 can present unique risks to a patient as</p> <p>22 opposed to just contraction of tissue that</p> <p>23 isn't surrounding mesh?</p> <p>24 MS. VAN STEENBURGH: Object to</p>

<p style="text-align: right;">Page 258</p> <p>1 form.</p> <p>2 THE WITNESS: I don't</p> <p>3 understand the difference.</p> <p>4 BY MR. FAES:</p> <p>5 Q Well, we've discussed the fact that tissue</p> <p>6 contraction can occur in every surgery;</p> <p>7 right?</p> <p>8 A Right.</p> <p>9 Q But when there's mesh involved and tissue</p> <p>10 contraction occurs, that means that the mesh</p> <p>11 can shrink as well because it's -- if it's</p> <p>12 encapsulated within that shrinking tissue;</p> <p>13 right?</p> <p>14 A Anywhere there's scarring, there's</p> <p>15 contracture.</p> <p>16 Q Right.</p> <p>17 A There's scarring from any surgery.</p> <p>18 Q So, my question is: Do you believe that the</p> <p>19 contracture of that mesh in a procedure that</p> <p>20 involved mesh presents unique risks to the</p> <p>21 patient?</p> <p>22 MS. VAN STEENBURGH: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: Such a play with</p>	<p style="text-align: right;">Page 260</p> <p>1 implanted as directed in the IFU."</p> <p>2 Is that an opinion you intend to</p> <p>3 offer in this case?</p> <p>4 A Yes.</p> <p>5 Q So, if it's not implanted as directed in the</p> <p>6 IFU, do you believe the TVT mesh can curl?</p> <p>7 A Yes.</p> <p>8 Q Do you believe that the only time the TVT</p> <p>9 mesh can curl is if it's not implanted</p> <p>10 correctly?</p> <p>11 A That, I can't say.</p> <p>12 Q Do you believe that the TVT mesh can rope if</p> <p>13 it's not implanted as directed in the IFU?</p> <p>14 A There has to be some tension.</p> <p>15 Q Do you believe that the only way that the</p> <p>16 TVT mesh can rope is if it's not implanted</p> <p>17 as directed in the IFU?</p> <p>18 MS. VAN STEENBURGH: Object to</p> <p>19 form.</p> <p>20 THE WITNESS: There's maybe a</p> <p>21 possibility if the patient is doing too</p> <p>22 strenuous exercise or having intercourse too</p> <p>23 early that they can put some tension on the</p> <p>24 tape. I think if they follow the rules and</p>
<p style="text-align: right;">Page 259</p> <p>1 words. It's scarring around the mesh.</p> <p>2 Scarring around the cut is always there. And</p> <p>3 that has to be taken into consideration when</p> <p>4 you do these things. The mesh itself I don't</p> <p>5 believe shrinks.</p> <p>6 BY MR. FAES:</p> <p>7 Q So, do you think that nerves can become</p> <p>8 entrapped in the interstices of the mesh and</p> <p>9 that can cause pain as the mesh shrinks in a</p> <p>10 patient?</p> <p>11 MS. VAN STEENBURGH: Objection.</p> <p>12 THE WITNESS: Yes. If you put</p> <p>13 the mesh over a nerve, yes; or on the nerve</p> <p>14 or in a nerve, yes.</p> <p>15 BY MR. FAES:</p> <p>16 Q And, in fact, have you reviewed any kind of</p> <p>17 documents or anything from Ethicon and</p> <p>18 Johnson & Johnson indicating that that was a</p> <p>19 concern with their pelvic meshes?</p> <p>20 A I can't recall exactly the document. But</p> <p>21 it's a fact and known, yes.</p> <p>22 Q So, you state that in your experience, "the</p> <p>23 TVT mesh does not curl, rope, shrink,</p> <p>24 contract, or experience poor collapse when</p>	<p style="text-align: right;">Page 261</p> <p>1 don't lift too heavy, don't exercise too</p> <p>2 heavy, don't have intercourse for a while,</p> <p>3 the mesh will heal in flat. If they do</p> <p>4 strenuous things, I don't know if this has</p> <p>5 ever been tested, but it's a thought that</p> <p>6 maybe there's tension on it, it can do it.</p> <p>7 But I think most of the time when there's</p> <p>8 issues with the mesh, it's because it's been</p> <p>9 tugged on during surgery.</p> <p>10 BY MR. FAES:</p> <p>11 Q So, do you believe that the TVT mesh can</p> <p>12 shrink or contract if it's not implanted as</p> <p>13 directed in the IFU?</p> <p>14 MS. VAN STEENBURGH: Objection,</p> <p>15 form.</p> <p>16 THE WITNESS: If it shrinks,</p> <p>17 you can end up with overcorrection, and we</p> <p>18 test for that. Every person gets tested. If</p> <p>19 it is on the tight side by the surgeon and</p> <p>20 then it shrinks a little bit, scars a little</p> <p>21 bit, possibly. We look for it and we deal</p> <p>22 with it if it is there.</p> <p>23 BY MR. FAES:</p> <p>24 Q But my question is: Do you believe that the</p>

<p style="text-align: right;">Page 262</p> <p>1 TVT mesh can shrink or contract even if it's</p> <p>2 implanted exactly as directed in the IFU, or</p> <p>3 instructions for use?</p> <p>4 MS. VAN STEENBURGH: Object to</p> <p>5 form.</p> <p>6 THE WITNESS: Unlikely. But</p> <p>7 could it possibly? Probably. If she's</p> <p>8 overactive. I don't know how she would get</p> <p>9 tension on it after it's in. I can't say</p> <p>10 never.</p> <p>11 BY MR. FAES:</p> <p>12 Q Do you believe that the TVT mesh can</p> <p>13 experience poor collapse when -- strike</p> <p>14 that.</p> <p>15 Do you believe that the TVT mesh can</p> <p>16 experience poor collapse if it's not</p> <p>17 implanted as directed in the IFU?</p> <p>18 A Yeah. If it's tugged on.</p> <p>19 Q So, do you think the only way that a TVT</p> <p>20 mesh can experience poor collapse is if it's</p> <p>21 put in wrong?</p> <p>22 MS. VAN STEENBURGH: Object to</p> <p>23 form.</p> <p>24 THE WITNESS: These are</p>	<p style="text-align: right;">Page 264</p> <p>1 BY MR. FAES:</p> <p>2 Q So, you don't believe that different</p> <p>3 patients can have different reactions to the</p> <p>4 TVT mesh where some might have a significant</p> <p>5 inflammatory response which could cause a</p> <p>6 lot of contracture but another person might</p> <p>7 not have the same reaction to the mesh?</p> <p>8 MS. VAN STEENBURGH: Object to</p> <p>9 form.</p> <p>10 THE WITNESS: If that was a big</p> <p>11 problem, we would see a lot more patients</p> <p>12 with obstruction after it was put in.</p> <p>13 BY MR. FAES:</p> <p>14 Q How many patients -- what percentage of</p> <p>15 patients would you need to see in order for</p> <p>16 you to conclude that there was a significant</p> <p>17 problem with mesh contracture?</p> <p>18 A I can't give you a number. A statistician</p> <p>19 would have to give you that. I can say that</p> <p>20 when we put slings in, if over time there's</p> <p>21 anything that happened is that some of them</p> <p>22 will start leaking after a while indicating</p> <p>23 that there's more slacking than shrinking.</p> <p>24 I don't think shrinking of a sling after</p>
<p style="text-align: right;">Page 263</p> <p>1 questions that are asking for absolute</p> <p>2 answers. I can't give you absolute answers</p> <p>3 for almost anything in medicine.</p> <p>4 BY MR. FAES:</p> <p>5 Q You go on to state here that "If the TVT</p> <p>6 mesh had significant contracture, it would</p> <p>7 contract uniformly, chronically elevating</p> <p>8 the bladder and leaving almost all patients</p> <p>9 with voiding dysfunction."</p> <p>10 Do you see that?</p> <p>11 A Yes, that's what I'm saying.</p> <p>12 Q So, it's your belief that in order for the</p> <p>13 TVT mesh to have significant contracture,</p> <p>14 that all patients have to experience the</p> <p>15 same kind of uniform contraction?</p> <p>16 MS. VAN STEENBURGH: Object to</p> <p>17 form.</p> <p>18 THE WITNESS: Yeah. It's like</p> <p>19 if I put a rope around your neck and tighten</p> <p>20 it so you almost couldn't breathe, that's the</p> <p>21 way the things have to be to work. And then</p> <p>22 the rope shrunk, you wouldn't be able to</p> <p>23 breathe. We wouldn't know it.</p> <p>24</p>	<p style="text-align: right;">Page 265</p> <p>1 it's been put in is a big problem or we</p> <p>2 would have seen it. It's more like if I can</p> <p>3 get her dry today, she's more likely to leak</p> <p>4 after a while than she is to become</p> <p>5 obstructed after a while.</p> <p>6 Q Well, what percentage of patients would you</p> <p>7 need to see with shrinkage or contraction of</p> <p>8 the sling before you would conclude that the</p> <p>9 device is not -- that the design of the</p> <p>10 device is not reasonable?</p> <p>11 A That's a statistical question and I cannot</p> <p>12 answer that.</p> <p>13 Q So, you don't have any objective standard</p> <p>14 that you're applying for your opinion that</p> <p>15 the fact that the TVT mesh can shrink is not</p> <p>16 a defect or problem with the mesh?</p> <p>17 A If it shrunk, it probably would be a good</p> <p>18 thing. It would be leaking less. The</p> <p>19 problem is that you may not hold tight</p> <p>20 forever and some start leaking after a</p> <p>21 while. Sometimes we even put in a new</p> <p>22 sling. I cannot remember any that have had</p> <p>23 a normal post procedure after surgery and</p> <p>24 then a month or two or three later have</p>

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<p>1 retention. I haven't seen that. I would</p> <p>2 have to see at least one before I would</p> <p>3 start thinking that's an issue.</p> <p>4 Q So, how many would it take? Would it take</p> <p>5 more than one?</p> <p>6 A It would take at least one. I haven't seen</p> <p>7 one yet. If they're too tight, they're too</p> <p>8 tight the day of or the day after surgery.</p> <p>9 We even let them go for a while to see if</p> <p>10 they loosen up over time. We don't look for</p> <p>11 them to tighten. If someone has this thing</p> <p>12 too tight, it doesn't help to let her go for</p> <p>13 a month to see if it tightens up.</p> <p>14 Theoretically, it might be a problem. In</p> <p>15 reality, it's not a problem.</p> <p>16 Q So, you've never seen reports in the medical</p> <p>17 literature of someone who developed urinary</p> <p>18 retention after the TVT sling -- a year</p> <p>19 after the TVT was implanted?</p> <p>20 A I haven't seen that.</p> <p>21 Q Okay.</p> <p>22 A Not that I can recall.</p> <p>23 Q If there were reports in the medical</p> <p>24 literature that indicated that to be the</p>	<p>1 I'm looking for -- I don't see it being</p> <p>2 clinically significant.</p> <p>3 Q So, you do believe -- but you do believe</p> <p>4 that the TVT mesh degrades in vivo?</p> <p>5 A I've seen some theories about it. I know a</p> <p>6 lot of people don't believe in it. I have</p> <p>7 never seen it being a clinical relevance. I</p> <p>8 don't know what the relevance is.</p> <p>9 Q Would you agree with me that if the</p> <p>10 degradation of the TVT is shown to have</p> <p>11 clinical significance, that that would</p> <p>12 indicate a problem or defect with the mesh?</p> <p>13 MS. VAN STEENBURGH: Object to</p> <p>14 form.</p> <p>15 THE WITNESS: I can't answer</p> <p>16 that.</p> <p>17 BY MR. FAES:</p> <p>18 Q What would you need to know in order to</p> <p>19 answer that?</p> <p>20 A I know so little about degradation. I have</p> <p>21 never seen it or heard of it being a</p> <p>22 problem. It's not something we deal with or</p> <p>23 worry about. So, I just cannot make a</p> <p>24 statement. I think it's clinically</p>
Page 267	Page 269
<p>1 case, is that something you want to see</p> <p>2 before you form any opinions on it?</p> <p>3 A Yeah, I'd be interested in it. I haven't</p> <p>4 seen it that I can recall.</p> <p>5 Q So, that might change your opinion regarding</p> <p>6 whether or not the TVT mesh shrinks or</p> <p>7 contracts, if there were multiple reports of</p> <p>8 that in the medical literature?</p> <p>9 MS. VAN STEENBURGH: Object to</p> <p>10 form.</p> <p>11 THE WITNESS: I don't see the</p> <p>12 point of contracting or not contracting. I'm</p> <p>13 looking for a healthy patient that don't leak</p> <p>14 and don't have pain.</p> <p>15 BY MR. FAES:</p> <p>16 Q So, I'm looking at your next paragraph in</p> <p>17 your expert report regarding degradation.</p> <p>18 And let me just start off with this</p> <p>19 question, because your report's a little bit</p> <p>20 unclear to me.</p> <p>21 Is it your opinion that the TVT mesh</p> <p>22 doesn't degrade in vivo or that it degrades</p> <p>23 but it's not clinically significant?</p> <p>24 A I don't see it being clinically significant.</p>	<p>1 irrelevant.</p> <p>2 Q In your report on the following page, you</p> <p>3 state that based on your experience and from</p> <p>4 the literature, "there's no difference</p> <p>5 between laser-cut versus mechanically cut</p> <p>6 mesh from a clinical standpoint."</p> <p>7 Do you see that?</p> <p>8 A Yes.</p> <p>9 Q And that's an opinion you intend to offer in</p> <p>10 this case?</p> <p>11 A Yeah. I don't think there's really that</p> <p>12 much practical difference except in the</p> <p>13 ending of it.</p> <p>14 Q So, you don't think there's that much</p> <p>15 difference or you think there's no</p> <p>16 difference?</p> <p>17 A There's a slight difference, like I talked</p> <p>18 about earlier today.</p> <p>19 Q I think I already asked you enough about</p> <p>20 your clinical experience on that point, but</p> <p>21 I want to ask with regard to the literature,</p> <p>22 are you aware of any randomized clinical</p> <p>23 study specifically comparing laser-cut TVT</p> <p>24 mesh to mechanically cut TVT mesh with</p>

<p style="text-align: right;">Page 270</p> <p>1 regard to safety?</p> <p>2 A I believe I've seen article about it.</p> <p>3 Q Which articles?</p> <p>4 A I can't recall right now. If you put it in</p> <p>5 front of me, I'll look at it. But I just</p> <p>6 don't recall the article right now.</p> <p>7 Q Same question with regard to TVT-O. Do you</p> <p>8 think that there's been any randomized</p> <p>9 clinical -- strike that.</p> <p>10 Are you aware of any randomized,</p> <p>11 controlled clinical study specifically</p> <p>12 evaluating safety comparing the laser-cut</p> <p>13 TVT to the mechanically cut TVT-O?</p> <p>14 A I think everything we use now is laser cut.</p> <p>15 I don't see the relevance of the whole</p> <p>16 discussion of one versus the other. I don't</p> <p>17 think there's more incontinence if you use</p> <p>18 one or the other.</p> <p>19 Q So, you've issued an opinion in this case</p> <p>20 that you believe that the design of the TVT</p> <p>21 is reasonably safe; right?</p> <p>22 A Yes.</p> <p>23 Q Would you agree with me that with regard to</p> <p>24 erosions, there could be a level of erosion</p>	<p style="text-align: right;">Page 272</p> <p>1 A No, no. I don't believe it has as much to</p> <p>2 do with the sling itself as it has to do</p> <p>3 with the condition of the tissue in the</p> <p>4 woman, her age and years of estrogen, and</p> <p>5 the surgeon's surgical technique.</p> <p>6 Q So, theoretically, a study -- strike that.</p> <p>7 Theoretically, the TVT device could</p> <p>8 have an erosion rate of 99 percent, erosion</p> <p>9 exposure, extrusion rate of 99 percent, and</p> <p>10 you might still find that the design of that</p> <p>11 device is safe for its intended use?</p> <p>12 MS. VAN STEENBURGH: Object to</p> <p>13 form.</p> <p>14 THE WITNESS: I've never heard</p> <p>15 of an erosion rate of 99 percent. It</p> <p>16 probably wouldn't even be on the market.</p> <p>17 BY MR. FAES:</p> <p>18 Q That's kind of what I'm getting at, Doctor.</p> <p>19 What percentage of erosions,</p> <p>20 extrusions, and exposures combined would</p> <p>21 indicate to you that that device, like the</p> <p>22 TVT, is not acceptable for its intended use</p> <p>23 for stress urinary incontinence?</p> <p>24 MS. VAN STEENBURGH: Object to</p>
<p style="text-align: right;">Page 271</p> <p>1 seen with the TVT where that could indicate</p> <p>2 that that device -- that the design of that</p> <p>3 device was not safe?</p> <p>4 MS. VAN STEENBURGH: Object to</p> <p>5 form.</p> <p>6 THE WITNESS: I don't believe</p> <p>7 that. Erosion is when it goes into the</p> <p>8 urethra. And it's very easy to cut the</p> <p>9 urethra if you're not experienced enough.</p> <p>10 I've seen people do that.</p> <p>11 BY MR. FAES:</p> <p>12 Q I think I asked a bad question, so let me</p> <p>13 try to ask another one.</p> <p>14 Would you agree that there could be a</p> <p>15 rate of erosions, extrusions, and exposures</p> <p>16 seen with a stress urinary device like the</p> <p>17 TVT that would indicate to you that that</p> <p>18 device is not reasonably safe for use?</p> <p>19 MS. VAN STEENBURGH: Object to</p> <p>20 form.</p> <p>21 THE WITNESS: No, no.</p> <p>22 BY MR. FAES:</p> <p>23 Q So, there's no percentage in your mind that</p> <p>24 that --</p>	<p style="text-align: right;">Page 273</p> <p>1 form.</p> <p>2 THE WITNESS: I cannot give you</p> <p>3 a figure. It has no base in clinical</p> <p>4 practice, the question. It's far more that</p> <p>5 goes into a decision on using a sling than a</p> <p>6 number in a hypothetical case.</p> <p>7 BY MR. FAES:</p> <p>8 Q And I assume that you're --</p> <p>9 A It makes no sense.</p> <p>10 Q So, you can't articulate any objective</p> <p>11 standard that you're applying for an</p> <p>12 acceptable complication rate for the TVT or</p> <p>13 TVT-O to conclude that the design is</p> <p>14 reasonably safe for its intended use?</p> <p>15 A That's for a researcher to do that. As far</p> <p>16 as I'm concerned, the TVT is very, very</p> <p>17 safe. We put them in a variety of patients</p> <p>18 with other issues that don't come up here.</p> <p>19 Q Are you familiar with -- well, strike that</p> <p>20 and let me back up.</p> <p>21 As you sit here today, are there any</p> <p>22 medical devices for the treatment of stress</p> <p>23 urinary incontinence that you consider to be</p> <p>24 not reasonably safe for its intended use?</p>

<p style="text-align: right;">Page 274</p> <p>1 A Not reasonably safe?</p> <p>2 Q Yes.</p> <p>3 A No. The ones we use, I think they're all</p> <p>4 reasonably safe.</p> <p>5 Q So, I guess my question is: If you're</p> <p>6 concluding that the design of the TVT and</p> <p>7 TVT-O devices is reasonably safe, how would</p> <p>8 I know a design of an SUI device wasn't</p> <p>9 reasonably safe?</p> <p>10 MS. VAN STEENBURGH: Object to</p> <p>11 form.</p> <p>12 THE WITNESS: You would have to</p> <p>13 ask people who are in the business of</p> <p>14 designing them. I'm in the business of using</p> <p>15 it. I think it's a very safe product,</p> <p>16 compared to the other option which is far</p> <p>17 more invasive surgery with its own risks. It</p> <p>18 may not be a risk of erosion but there are</p> <p>19 other risks involved.</p> <p>20 BY MR. FAES:</p> <p>21 Q So, is there any objective standard that you</p> <p>22 can give me to where you would say that a</p> <p>23 device for the treatment of stress urinary</p> <p>24 incontinence is not reasonably safe for its</p>	<p style="text-align: right;">Page 276</p> <p>1 Do you see that?</p> <p>2 A That's correct.</p> <p>3 Q What's that referring to?</p> <p>4 A We're doing a clinical study on a product</p> <p>5 for muscle training.</p> <p>6 Q What product is that?</p> <p>7 A It is a sensor that senses when she's using</p> <p>8 the right muscles to guide her in</p> <p>9 exercising.</p> <p>10 Q Is that a medical device?</p> <p>11 A It is a medical device that is -- I think</p> <p>12 the FDA doesn't consider it risky or</p> <p>13 dangerous. You can almost go and sell it.</p> <p>14 It's almost like a vibrator. The study is</p> <p>15 being done at the University of Minnesota, a</p> <p>16 university in Seattle, and our group. And</p> <p>17 it basically has to do with training of</p> <p>18 muscles in the pelvic floor.</p> <p>19 Q Last question.</p> <p>20 What's it called and who makes it?</p> <p>21 A It's not in production yet. I don't even</p> <p>22 know what the name of it is.</p> <p>23 MS. VAN STEENBURGH: And I</p> <p>24 don't know if you're under some kind of</p>
<p style="text-align: right;">Page 275</p> <p>1 intended use?</p> <p>2 A No, I cannot give you that.</p> <p>3 (Exhibit No. 20 Marked.)</p> <p>4</p> <p>5 MS. VAN STEENBURGH: How much</p> <p>6 time do we have left?</p> <p>7 THE COURT REPORTER: None.</p> <p>8 MR. FAES: Sixty more seconds?</p> <p>9 MS. VAN STEENBURGH: Sure.</p> <p>10 BY MR. FAES:</p> <p>11 Q Doctor, I'm handing you what's been marked</p> <p>12 as Exhibit No. 20. This is a printout that</p> <p>13 I took yesterday from your website.</p> <p>14 Do you see that?</p> <p>15 A Yes.</p> <p>16 Q And that's you at the top?</p> <p>17 A Yes.</p> <p>18 Q And is that your partner, Dr. Hallman?</p> <p>19 A Hallman. Yes.</p> <p>20 Q If you look over on the left side, "If you</p> <p>21 suffer from urinary incontinence and would</p> <p>22 like free treatments as part of a new study,</p> <p>23 please click here to contact us for more</p> <p>24 information."</p>	<p style="text-align: right;">Page 277</p> <p>1 agreement in terms of confidentiality.</p> <p>2 MR. FAES: I'm just curious who</p> <p>3 makes it.</p> <p>4 THE WITNESS: I don't know.</p> <p>5 The study hasn't even started.</p> <p>6 MR. FAES: Fair enough. I have</p> <p>7 many more questions for you, but I'm out of</p> <p>8 time.</p> <p>9 THE WITNESS: I'm in the</p> <p>10 process of taking a class on confidentiality</p> <p>11 and studies.</p> <p>12 MS. VAN STEENBURGH: All right.</p> <p>13 I have a few questions but I need to take a</p> <p>14 break and get a couple of documents.</p> <p>15 (Recess began - 3:10 p.m.)</p> <p>16 (Recess ended - 3:20 p.m.)</p> <p>17 EXAMINATION</p> <p>18 BY MS. VAN STEENBURGH:</p> <p>19 Q Doctor, you were asked some questions about</p> <p>20 what would or wouldn't be an acceptable or</p> <p>21 unacceptable rate of complications. So, for</p> <p>22 example, erosion.</p> <p>23 Do you remember those questions?</p> <p>24 A Yes.</p>

<p style="text-align: right;">Page 278</p> <p>1 Q So, what is acceptable or not acceptable, is 2 that the analysis, or is there a 3 risk/benefit analysis when you're looking at 4 patients? In science, is there any 5 absolute, acceptable rate? 6 A I don't know if there's an absolute. 7 Q Right. And so when you talk with your 8 patients, what are you analyzing in terms of 9 what you provide relative to the risks and 10 benefits to them? 11 A Well, I sit and I draw pictures and I 12 explain and I go over the benefits of the 13 surgery and the risks involved. I can guide 14 them a little bit. Some of them have very 15 strong opinions. Some ask me what I 16 recommend. I have to make sure I go over 17 the risks as well as the benefits. 18 Q And as part of your analysis of what those 19 risks and benefits are, you've taken a look 20 at some of the literature, have you not? 21 A Right. 22 Q And you've taken a look at some of the 23 complication rates? 24 A Right.</p>	<p style="text-align: right;">Page 280</p> <p>1 THE WITNESS: Yes. 2 BY MS. VAN STEENBURGH: 3 Q And what was the complication rate that the 4 authors found based on their analysis here? 5 What was the percentage that -- 6 A What page are you on? 7 Q What was the percentage that underwent 8 removal or revision? 9 A What page? 10 Q E3. 11 A Here it is. Okay. 2.2 percent. 12 Q And is that consistent with what you see in 13 your practice, Doctor? 14 MR. FAES: Object to form. 15 THE WITNESS: Yes. It's more 16 in that range. 17 BY MS. VAN STEENBURGH: 18 Q And Doctor, as part of your practice, do you 19 perform removal on patients that you have 20 not implanted mesh -- for whom you have not 21 implanted mesh? 22 A Yes. 23 Q Okay. So, you are referring, Doctor, from 24 other doctors; is that right?</p>
<p style="text-align: right;">Page 279</p> <p>1 Q I'm going to show you a couple of things. 2 (Exhibit No. 21 Marked.) 3 4 BY MS. VAN STEENBURGH: 5 Q Doctor, I'm showing you what's marked as 6 Deposition Exhibit No. 21. This is an 7 article by first author of Welk. 8 And that's something that's on your 9 reliance list, is it not? 10 A Yes. 11 Q Okay. And this article is entitled, 12 "Removal or Revision of Vaginal Mesh Used 13 for the Treatment of Stress Urinary 14 Incontinence"; correct? 15 A Yes. 16 Q All right. And if you'd go to page E3, this 17 was an analysis of -- they identified over 18 59,000 women who underwent procedures for 19 stress urinary incontinence and overall 1307 20 underwent mesh removal or revision after 21 having received a mesh implant for stress 22 urinary incontinence. 23 Do you see that there? 24 MR. FAES: Object to form.</p>	<p style="text-align: right;">Page 281</p> <p>1 A Yes. 2 Q So, some of your patient population includes 3 mesh removal for patients who had a 4 different person as an implanter; is that 5 right? 6 A That's correct. 7 Q And Doctor, when you tell patients about 8 what the possible percentage is that they 9 may have to go in for mesh removal, is that 10 a number that you give to them as one of the 11 risks and benefits that you talk about? 12 A Yes. I don't have a log of my own, so I 13 have to quote pretty much what's in the 14 literature. And this is a number that comes 15 up. 2.2 percent. 16 Q And is that consistent with other literature 17 that you reviewed in connection with the 18 risk factors for the midurethral sling 19 revision? 20 MR. FAES: Object to form. 21 THE WITNESS: Say that again. 22 BY MS. VAN STEENBURGH: 23 Q And is that number consistent with other 24 studies that you've reviewed regarding the</p>

<p style="text-align: right;">Page 282</p> <p>1 risk for revision for the midurethral sling?</p> <p>2 MR. FAES: Object to form.</p> <p>3 THE WITNESS: That's correct.</p> <p>4 BY MS. VAN STEENBURGH:</p> <p>5 Q Doctor, with respect to the article that you</p> <p>6 were shown in the Minnesota Physician, when</p> <p>7 there's a reference to the use of the da</p> <p>8 Vinci Surgical System, that is for mesh</p> <p>9 removal and reconstructive surgery. That's</p> <p>10 not something that you use to put in slings;</p> <p>11 correct?</p> <p>12 A That's correct.</p> <p>13 Q And that's something used for prolapse</p> <p>14 surgery as well; correct?</p> <p>15 A That's correct.</p> <p>16 Q So, in this article, are you talking about</p> <p>17 slings and prolapse surgery?</p> <p>18 A That is something that was put in there</p> <p>19 around the time when I also sent out letters</p> <p>20 to doctors in the area about removal of mesh</p> <p>21 using a robot to avoid cutting in the</p> <p>22 vagina, and that's what it's alluded to</p> <p>23 there. It's a newer way of removing mesh</p> <p>24 causing less harm.</p>	<p style="text-align: right;">Page 284</p> <p>1 of mesh as a treatment for stress urinary</p> <p>2 incontinence?</p> <p>3 MR. FAES: Object to form.</p> <p>4 THE WITNESS: Yes.</p> <p>5 BY MS. VAN STEENBURGH:</p> <p>6 Q Is neuromuscular pain or problems, is that a</p> <p>7 risk or possible complication from any</p> <p>8 pelvic surgery?</p> <p>9 MR. FAES: Object to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. VAN STEENBURGH:</p> <p>12 Q And that's not unique to mesh, is it?</p> <p>13 MR. FAES: Object to form.</p> <p>14 THE WITNESS: No.</p> <p>15 BY MS. VAN STEENBURGH:</p> <p>16 Q Is urge incontinence a possible risk or</p> <p>17 complication from any pelvic surgery?</p> <p>18 MR. FAES: Object to form.</p> <p>19 THE WITNESS: Yes, it is.</p> <p>20 BY MS. VAN STEENBURGH:</p> <p>21 Q And is that a complication or risk that is</p> <p>22 unique to mesh?</p> <p>23 MR. FAES: Object to form.</p> <p>24 THE WITNESS: No.</p>
<p style="text-align: right;">Page 283</p> <p>1 Q Doctor, you talked a little bit about some</p> <p>2 of the complications -- or counsel asked you</p> <p>3 some questions about complications relating</p> <p>4 to mesh surgery. And one of them is acute</p> <p>5 and chronic pain.</p> <p>6 Do you recall that?</p> <p>7 A Yes.</p> <p>8 Q Is that a risk or possible complication with</p> <p>9 any pelvic surgery?</p> <p>10 A Yes.</p> <p>11 Q And is that something that was known as a</p> <p>12 risk or complication relative to pelvic</p> <p>13 surgery prior to the use of mesh?</p> <p>14 MR. FAES: Object to form.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MS. VAN STEENBURGH:</p> <p>17 Q Same question about dyspareunia.</p> <p>18 I think you indicated that</p> <p>19 dyspareunia is a risk or complication for</p> <p>20 any pelvic surgery; is that correct?</p> <p>21 A That's correct.</p> <p>22 Q And based upon your experience and your</p> <p>23 knowledge, was that a risk that was known to</p> <p>24 yourself or other surgeons prior to the use</p>	<p style="text-align: right;">Page 285</p> <p>1 BY MS. VAN STEENBURGH:</p> <p>2 Q What about urinary frequency? Is that a</p> <p>3 risk or complication of general pelvic</p> <p>4 surgery?</p> <p>5 MR. FAES: Object to form.</p> <p>6 THE WITNESS: Yes, it is.</p> <p>7 BY MS. VAN STEENBURGH:</p> <p>8 Q And is that a risk or complication that is</p> <p>9 unique to mesh?</p> <p>10 MR. FAES: Object to form.</p> <p>11 THE WITNESS: No.</p> <p>12 BY MS. VAN STEENBURGH:</p> <p>13 Q And finally, urinary retention, is that a</p> <p>14 risk or complication that is consistent</p> <p>15 with -- one of the risks or complications</p> <p>16 for any pelvic surgery?</p> <p>17 MR. FAES: Object to form.</p> <p>18 THE WITNESS: That is correct.</p> <p>19 BY MS. VAN STEENBURGH:</p> <p>20 Q Okay. Is that a unique risk or complication</p> <p>21 to mesh?</p> <p>22 MR. FAES: Object to form.</p> <p>23 THE WITNESS: No.</p> <p>24</p>

<p style="text-align: right;">Page 286</p> <p>1 BY MS. VAN STEENBURGH:</p> <p>2 Q Doctor, you mentioned that you thought that</p> <p>3 the information provided in the IFU was</p> <p>4 adequate or satisfactory. And I think you</p> <p>5 mentioned something about the IFU is not</p> <p>6 necessarily the only source of information</p> <p>7 that a physician relies on.</p> <p>8 Do you remember that testimony?</p> <p>9 MR. FAES: Object to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. VAN STEENBURGH:</p> <p>12 Q What are some of the other sources, if any,</p> <p>13 that you as a clinician rely on besides the</p> <p>14 IFU?</p> <p>15 A Published articles, review courses,</p> <p>16 continuing medical education. I belong to</p> <p>17 an organization called Minimal Invasive</p> <p>18 Surgery and Pelvis. So, it's a whole body</p> <p>19 of information.</p> <p>20 Q So, to summarize, you said that information</p> <p>21 regarding risks or complications include the</p> <p>22 literature; is that right?</p> <p>23 A Yes.</p> <p>24 Q And seminars and other things that you</p>	<p style="text-align: right;">Page 288</p> <p>1 A No.</p> <p>2 Q Doctor, you indicated that you have removed</p> <p>3 slings where there has been no extrusion and</p> <p>4 you said that sometimes you've seen that</p> <p>5 it's been placed in the wrong place, that</p> <p>6 it's too tight or too loose and sometimes</p> <p>7 for pain.</p> <p>8 Do you remember that?</p> <p>9 MR. FAES: Object to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. VAN STEENBURGH:</p> <p>12 Q In the cases regarding pain, what, if any,</p> <p>13 conclusion have you reached as to whether</p> <p>14 the mesh is the cause of that pain?</p> <p>15 MR. FAES: Object to form.</p> <p>16 THE WITNESS: It's extremely</p> <p>17 important that it's inserted correctly. And</p> <p>18 if it's deviated from the perfect position,</p> <p>19 there's a much greater chance there could be</p> <p>20 pain involved. Most of the slings that I go</p> <p>21 in and take out for pain are sitting wrong.</p> <p>22 BY MS. VAN STEENBURGH:</p> <p>23 Q And Doctor, as I understand it, you have</p> <p>24 implanted the TVT, both the mechanically cut</p>
<p style="text-align: right;">Page 287</p> <p>1 attend.</p> <p>2 MR. FAES: Object to form.</p> <p>3 THE WITNESS: Yes.</p> <p>4 BY MS. VAN STEENBURGH:</p> <p>5 Q Conversations with colleagues?</p> <p>6 MR. FAES: Object to form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MS. VAN STEENBURGH:</p> <p>9 Q And your own clinical experience?</p> <p>10 MR. FAES: Object to form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MS. VAN STEENBURGH:</p> <p>13 Q Doctor, are you aware of any studies</p> <p>14 regarding the safety or efficacy of using</p> <p>15 Ultrapro as a material for a urinary sling?</p> <p>16 A I don't think so. I can't recall.</p> <p>17 Q Have you seen any scientific evidence</p> <p>18 showing that Ultrapro would be a safer or</p> <p>19 more effective material for a stress urinary</p> <p>20 sling?</p> <p>21 A No.</p> <p>22 Q Do you even know when Ultrapro became</p> <p>23 available as a material for any use in any</p> <p>24 mesh product?</p>	<p style="text-align: right;">Page 289</p> <p>1 mesh as well as a laser-cut mesh for that</p> <p>2 product; right?</p> <p>3 A Right.</p> <p>4 Q And in your clinical experience, have you</p> <p>5 noted any differences in terms of</p> <p>6 performance relative to efficacy, whether</p> <p>7 it's mechanically cut or laser cut?</p> <p>8 A No.</p> <p>9 Q And how about with respect to safety?</p> <p>10 A No.</p> <p>11 Q And is it -- my understanding is your</p> <p>12 testimony is your preference is for</p> <p>13 laser-cut mesh because of the way you like</p> <p>14 to handle it as a surgeon as opposed to any</p> <p>15 clinical impact on the patient?</p> <p>16 MR. FAES: Object to form.</p> <p>17 THE WITNESS: That's right.</p> <p>18 BY MS. VAN STEENBURGH:</p> <p>19 Q Doctor, in reaching your opinions in</p> <p>20 connection with the TVT and the TVT-O, do</p> <p>21 you differentiate in terms of the different</p> <p>22 kinds of levels of evidence that you</p> <p>23 consider important or significant?</p> <p>24 A Yes.</p>

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<p style="text-align: right;">Page 290</p> <p>1 Q And what are those levels of evidence?</p> <p>2 A One, two, and three.</p> <p>3 Q And what is level one evidence?</p> <p>4 A That is the one with the most appropriate</p> <p>5 statistics.</p> <p>6 Q So, a random, controlled study or meta</p> <p>7 analysis of that?</p> <p>8 A Correct.</p> <p>9 Q And what's level two?</p> <p>10 A Now you're testing me. Where's the pyramid?</p> <p>11 Q That's all right. We'll go to level three.</p> <p>12 Level three is about the case reports</p> <p>13 and those kind of things; right?</p> <p>14 A Yes. That's the least reliable.</p> <p>15 MR. FAES: Object to form.</p> <p>16 BY MS. VAN STEENBURGH:</p> <p>17 Q And in considering whether -- strike that.</p> <p>18 And in reviewing the literature in</p> <p>19 connection with your opinions relative to</p> <p>20 your report, what was the level of evidence</p> <p>21 that you relied on primarily for your</p> <p>22 opinions?</p> <p>23 A Level one studies.</p> <p>24 MS. VAN STEENBURGH: That's all</p>	<p style="text-align: right;">Page 292</p> <p>1 STATE OF MINNESOTA)</p> <p>2) ss.</p> <p>3 COUNTY OF SCOTT)</p> <p>4 Be it known that I took the deposition of RAGNVALD</p> <p>5 MJANGER, M.D. on the 20th day of July, 2017, in</p> <p>6 Minneapolis, Minnesota;</p> <p>7 That I was then and there a Notary Public in and for</p> <p>8 the County of Scott, State of Minnesota and that by</p> <p>9 virtue thereof, I was duly authorized to administer</p> <p>10 an oath;</p> <p>11 That the witness before testifying was by me first</p> <p>12 duly sworn to testify the whole truth and nothing but</p> <p>13 the truth relative to said cause;</p> <p>14 That the testimony of said witness was recorded in</p> <p>15 Stenotype by myself and transcribed into typewriting</p> <p>16 under my direction, and that the deposition is a true</p> <p>17 record of the testimony given by the witness to the</p> <p>18 best of my ability;</p> <p>19 That the cost of the original transcript has been</p> <p>20 charged to the party noticing the deposition, unless</p> <p>21 otherwise agreed upon by Counsel, and that copies</p> <p>22 have been made available to all parties at the same</p> <p>23 cost, unless otherwise agreed upon by Counsel;</p> <p>24 That I am not related to any of the parties hereto</p> <p>nor interested in the outcome of the action;</p> <p>That the reading and signing of the deposition by the</p> <p>witness and the Notice of filing were not waived;</p> <p>WITNESS MY HAND AND SEAL this 26th day of July, 2017.</p> <p>Sandra D. Burch, RPR, CRR</p> <p>My Commission expires January 31, 2020</p>
<p style="text-align: right;">Page 291</p> <p>1 I have. Thank you, Doctor.</p> <p>2</p> <p>3 (Time Noted: 3:35 p.m., Thursday, July</p> <p>4 20, 2017.)</p> <p>5 (The signature was reserved.)</p> <p>6</p> <p>7 * * * * *</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 293</p> <p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4 PAGE LINE CHANGE</p> <p>5</p> <p>6 REASON: _____</p> <p>7</p> <p>8 REASON: _____</p> <p>9</p> <p>10 REASON: _____</p> <p>11</p> <p>12 REASON: _____</p> <p>13</p> <p>14 REASON: _____</p> <p>15</p> <p>16 REASON: _____</p> <p>17</p> <p>18 REASON: _____</p> <p>19</p> <p>20 REASON: _____</p> <p>21</p> <p>22 REASON: _____</p> <p>23</p> <p>24 REASON: _____</p>

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
hereby certify that I have read the
foregoing pages, and that the same is
a correct transcription of the answers
given by me to the questions therein
propounded, except for the corrections or
changes in form or substance, if any,
noted in the attached Errata Sheet.

RAGNVALD MJANGER, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires: _____

Notary Public